PEER REVIEW

MANUAL

SAFER • HEALTHIER • PEOPLE™

CENTERS FOR DISEASE CONTROL AND PREVENTION

January 2001

Foreword

Peer review is a time-tested mechanism for evaluating the scientific and technical merit of research and training. It is a process that includes an independent assessment of the technical or scientific merit of research by peers who are scientists with knowledge and expertise equal to that of the researchers whose work they review and who provide signed assurances that their assessments are free of any real or perceived conflicts of interest. The processes discussed in the Peer Review Manual is an important step-by-step approach in carrying out this rigorous, standardized method of review for CDC-sponsored research grants and cooperative agreements.

The United States prides itself for its leadership position in basic biomedical research, yet, we fall behind many developed countries in life expectancy and other measures of health quality. Prevention research, one of CDC's highest priorities, is a multidisciplinary approach to discover new ways to prolong the health, well-being, and self-sufficiency of all Americans, enhancing the productivity of society.

The use of peer review at CDC will continue to grow over the next several years. Peer review is a dynamic system, and changes and improvements will lead to a distinctly CDC style in conducting peer review while maintaining the openness, quality, and credibility of the process. The manual will be updated on a regular basis to include these improvements.

The increasing use of the peer review process at CDC will continue to improve the transparency and accountability of the review process and will be greeted with enthusiasm by our external partners. With this foundation in scientific review excellence, we can confidently anticipate further successes in preventing disease, injury, and disability.

Special appreciation is expressed to Richard W. Sattin, MD, for his vision and leadership in matters related to peer review at the CDC including the need for this Peer Review Manual and for his valuable contribution as author and to Ruth L. Berkelman, MD, who supported and promoted the development of this Manual.

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Centers for Disease Control and Prevention

CDC Manual Outlline

INTRODUCTION

"Each Federal R&D Agency is expected to significantly enhance the utilization of merit review with peer evaluation and competitive selection in Federal R&D Projects. Research not subject to merit review with peer evaluation is expected to decline and funding in these areas should be moved into areas of merit reviewed research with peer evaluations."

White House Memorandum (OSTP & OMB) May 6, 1994

The concept of peer review, implemented and accepted by the scientific community long ago, has been largely responsible for the orderly development and growth of the biomedical research enterprise in this country. It has been used in many ways, but two are of particular note in the context of the support of research. The first is the requirement for peer review of publications of research results before appearing in prominent scientific journals. The second is the requirement to allocate funds for biomedical research on the basis of the peer review of competitive applications. Both have served to nurture and sustain the enormous growth of the research and training programs that currently exist and which are responsible for the significant scientific progress made in this century related to almost every disease and health-related problem that afflicts mankind. In terms of obtaining appropriations from Congress to continue and increase these efforts, peer review has served to provide the confidence that the funds will be properly spent and that a highly regarded peer review system exists for identifying and supporting meritorious research ideas and projects.

The purpose of this manual is to provide a suitable reference source to describe the practices, procedures, and policies for the peer review of competitive research and training applications received by the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR). Chapter I outlines the organizational structure of the CDC/ATSDR, along with its statement of mission and objectives. Chapter II provides assistance with the preparation of a Request for Applications (RFA) and similar solicitations of applications related to the specific priorities of CDC/ATSDR Centers, Institute, Offices (CIO). Chapter III presents an overview of the two-tiered peer review system for the evaluation of competitive research and training applications, policies related to the management of standing peer review committees and Special Emphasis Panels (SEPs), as well as a general description of staff responsibilities in carrying out the process. The next three chapters are devoted to the pre-meeting, on-site meeting, and post-meeting requirements for the first level of peer review panel review: initial scientific merit review. Chapter IV provides details of the necessary activities involved in preparing for a peer review meeting. Chapter V outlines activities and policies connected with the actual conduct of a peer review meeting. Chapter VI lists the essential post- meeting activities. Chapter VII presents information related to the second level of review: programmatic review. It highlights some of the key steps important to the functions and operating procedures of a secondary programmatic advisory committee. Chapter VIII is intended to amplify many of the important ethical issues and policies connected with the management of an extramural grants program. Appendix I contains RFA and Program Announcement templates to assist in the preparation of these documents. Appendix II presents orientation material that can be sent to SEP members to familiarize them the peer review process. Appendix III outlines briefly the many policies connected with grant award policies. Appendix IV includes some of the federal laws that directly impact the extramural grant programs.

Concurrent with the development of this manual, the Associate Director for Program Services, CDC is developing a CDC-wide Assistance Management Manual which establishes the policy basis for CDC's assistance management function from program planning through award closeout for all CDC staff. The Assistance Management Manual provides that grants and cooperative agreements may be awarded only on the basis of an independent review, wherein the review is conducted in accordance with specified standards and reviewers meet certain qualification criteria. One type of review process envisioned by that manual is peer review.

This Peer Review Manual elaborates on CDC's policy for use of peer review and attempts to provide as much guidance as possible to CIO staff in managing a peer review process. It provides the necessary background information and other details appropriate for CDC staff to understand the context within which CDC uses peer review, associated roles and responsibilities, the objectives of peer review, necessary procedures and controls, and documentation requirements. Therefore, the Peer Review Manual should be considered as providing a detailed implementation of the policy requirement for independent review alone, and should not be seen as duplicating the Assistance Management Manual. The Peer Review Manual may be relied on by those responsible for the peer review process; however, although this Manual addresses or references other aspects of the assistance management process, CDC staff should consult the Assistance Management Manual's treatment of those subjects to ensure compliance with all HHS/CDC policies and requirements.

The use of peer review at CDC will grow significantly over the next several years. Peer review is not a static system, but will constantly undergo changes and improvements based on evaluations by peer reviewers and CDC staff involved in the peer review process. These changes and improvements will lead to a distinctly CDC style in conducting peer review while maintaining the openness, quality, and credibility of the process. Thus, it is anticipated that this manual will be updated on a routine basis to incorporate these changes and will be included on the CDC intranet with links to other manuals involved in the assistance management function.

CHAPTER I
CDC Mission and Organization

CHAPTER CONTENT

ABOUT CDC: The Centers for Disease Control and Prevention (CDC), located in Atlanta, Ga., is an agency of the Department of Health and Human Services (DHHS) [CDC Web page (http://www.cdc.gov)].

CDC's Vision for the 21st Century

Healthy People in a Healthy World—Through Prevention

At CDC, we work hard to make people safer and healthier. By charting decisive courses of action, collecting the right information, and working closely with other health and community organizations, CDC has been putting science into action to tackle important health problems since 1946.

CDC MISSION

CDC's mission is promote health and quality of life by preventing and controlling disease, injury, and disability.

CDC seeks to accomplish its mission by working with partners throughout the nation and the world to monitor health, detect and investigate health problems, conduct research to enhance prevention, develop and advocate sound public health policies, implement prevention strategies, promote healthy behaviors, foster safe and healthful environments, and provide leadership and training.

Organization

The CDC is one of the major operating components of the DHHS. CDC's major organizational components respond individually in their areas of expertise and pool their resources and expertise on cross-cutting issues and specific health threats. The agency is comprised of these organizational components:

National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP): prevents premature death and disability from chronic diseases and promotes healthy personal behaviors.

National Center for Environmental Health (NCEH): provides national leadership in preventing and controlling disease, birth defects, disability, and death resulting from the interactions between people and their environment.

National Center for Health Statistics (NCHS)): provides statistical information that will guide actions and policies to improve the health of the American people.

National Center for Infectious Diseases INCID)): prevents illness, disability, and death caused by infectious diseases in the United States and around the world.

National Center for Injury Prevention and Control (NCIPC)): prevents death and disability from nonoccupational injuries, including those that are unintentional and those that result from violence.

National Institute for Occupational Safety and Health (NIOSH)): ensures safety and health for all people in the workplace through research and prevention.

National Center for HIV, STD, and TB Prevention (NCHSTP)): provides national leadership in preventing and controlling human immunodeficiency virus infection, sexually transmitted diseases, and tuberculosis.

National Immunization Program (NIP)): prevents disease, disability, and death from vaccine-preventable diseases in children and adults.

Epidemiology Program Office (EPO)): strengthens the public health system by coordinating public health surveillance; providing support in scientific communications, statistics, and epidemiology; and training in surveillance, epidemiology, and prevention effectiveness.

Public Health Practice Program Office (PHPPO)): strengthens community practice of public health by creating an effective workforce, building information networks, conducting practice research, and ensuring laboratory quality.

TYPICAL CENTER

Even though there are specific internal variations among the CDC components, all of which are hereafter referred to as "centers," a typical organizational pattern exists. Usually, both laboratory and clinical research are conducted directly by a center through its intramural program and are supported in other research organizations through an extramural program of grants and contracts. An extramural program is organized into specific scientific areas, each of which may provide research funding through grants, contracts, and cooperative agreements.

CDC performs many of the administrative functions for the Agency for Toxic Substances and Disease Registry (ATSDR), a sister agency of CDC, and one of eight federal public health agencies within DHHS. The Director of CDC also serves as the Administrator of ATSDR.

CDC Employees and Locations

Approximately 8,500 employees in 170 occupations

Locations:

- CDC facilities

  Anchorage, Alaska
  Atlanta, Georgia
  Cincinnati, Ohio
  Fort Collins, Colorado
  Morgantown, West Virginia
  Pittsburgh, Pennsylvania
  Research Triangle Park, North Carolina
  San Juan, Puerto Rico
  Spokane, Washington
  Washington, D.C. area

- Other countries
- Quarantine offices
- State and local health agencies

CDC Employees and Facilities in the Atlanta Area:

- Approximately 5,600 employees
- Headquarters on Clifton Road
- Remainder at other locations:

  Corporate Square
  Chamblee
  Decatur
  Executive Park
  Koger Center
  Lawrenceville
  Tucker

CDC includes 11 Centers, Institute, and Offices:

- National Center for Chronic Disease Prevention and Health Promotion
- National Center for Environmental Health

  Office of Genetics and Disease Prevention

- National Center for Health Statistics
- National Center for HIV, STD, and TB Prevention
- National Center for Infectious Diseases
- National Center for Injury Prevention and Control
- National Immunization Program
- National Institute for Occupational Safety and Health
- Epidemiology Program Office
- Public Health Practice Program Office
- Office of the Director

  Associate Director for Minority Health
  Associate Director for Science
  Freedom of Information Act Office
  Information Resources Management Office
  Management Analysis and Services Office
  National Vaccine Program Office
  Office of Communication, Division of Media Relations
  Office of Global Health
  Office of Health and Safety (OHASIS)
  Office of Women's Health
  Technology Transfer Office
  Washington, D.C. Office

PROCUREMENT and GRANTS OFFICE: The CDC's Procurement and Grants Office (PGO) is organizationally located within the Office of Program Support (OPS) in the Office of the Director, CDC. The office performs a variety of important duties related to the administration of Federal procurements and grants. The CDC's Small Business Program is also located in the Procurement and Grants Office.
In Fiscal Year 1999, PGO obligated approximately 2.6 billion dollars in contracts (including purchase orders), grants, and cooperative agreements. Additional organizational information on PGO can be obtained at http://www.cdc.gov/maso/opsfs.htm

Familiarity with the responsibilities and helpful advice that can be obtained from PGO will facilitate the management and administration of CIO grant and contract programs.

Because of the importance of the PGO to the CDC extramural grant programs, more specific information about the functioning of this office is provided below. The PGO:

- Provides technical and managerial direction for the development of CDC-wide policies, procedures, and practices in the acquisition, assistance, and materiel management areas.
- Participates with top management in program planning, policy determinations, evaluations, and decisions concerning acquisition, assistance, and materiel management.
- Provides direction for award, administration, and termination of contracts, purchase orders, grants, and cooperative agreements.
- Maintains a continuing review of CDC-wide acquisition, assistance management, and materiel management operations to assure adherence to laws, policies, procedures, and regulations.
- Maintains liaison with Department of Health and Human Servicdes (HHS),Public Health Service (PHS), General Services Administration (GSA), and other Federal agencies on acquisition, assistance, and materiel management policy, procedure, and operating matters.
- Provides administrative services and direction for budget, property, travel, and personnel of the PGO.
- Processes data for and maintains the contract information system for CDC/PHS/HHS.
- Operates CDC's Small and Disadvantaged Business Program and provides direction and support to various other socioeconomic programs encompassing the acquisition and assistance activities.

Cost Advisory Activity

As a procurement function, PGO has cost advisory responsibilities. PGO:

- Provides cost advisory services for contracts, grants, and cooperative agreements.
- Initiates requests for audits and evaluates and provides recommendations to contracting officer or grants management officer.
- As required, participates in negotiations with potential contractors and grantees.
- Develops overhead rates for profit and nonprofit organizations.
- Provides professional advice on accounting and cost principles in resolving audit exceptions as they relate to the acquisition and assistance processes.

Grants Management Branch (Atlanta)

The Grants Management Branch (GMB) is responsible for the awarding and administration of CDC's grants and cooperative agreements and those of the ATSDR.

Notices of opportunities to compete for grants and cooperative agreements are published in the Federal Register.

Application packets for current competitive program announcements may be requested by calling 1-888-GRANTS4, an automated voice mail system organized by program announcement number. The application packet can also be requested by e-mail to the grants specialist listed in the announcement or by e-mail to gmbinbox@cdc.gov. Application packets must be requested by program announcement number.

Current grant and cooperative agreement funding opportunities are available under a variety of program categories. To view a list of categories and program announcements, go to CDC's web page (**http://www.cdc.gov)** and click "Funding." Program announcements are provided only for those programs with current funding opportunities.

The major responsibilities of the GMB are to:

- Plan, direct, and conduct assistance management activities for CDC.
- Review assistance applications from a management point of view for conformity to laws, regulations, and policies, and negotiate and issue grant and cooperative agreement awards.
- Maintain official assistance files.
- Provide continuing surveillance of financial and administrative aspects of assistance supported activities to assure compliance with appropriate HHS, PHS, and CDC policies.
- Give technical assistance, where indicated, to improve the management of assistance supported activities and respond to requests for management information from headquarters, regional staffs, and the public.
- Develop, implement, and manage CDC assistance management procedures and policies.
- Provide for the collection and reporting of business management and programmatic data, and analyze and monitor business management data on grants and cooperative agreements.
- Conduct studies and provide guidance to improve the operation of management systems and review procedures.
- Maintain a close working relationship with CIOs and other CDC components that use grants and/or cooperative agreements in carrying out their missions.

GMB Service Sections, each of which is assigned to work with specific CIOs, have the following duties and responsibilities.

- Plan, direct, coordinate, and conduct the grants management functions and processes in
- Support of assistance awards, including cooperative agreements, discretionary grants, block grants, and formula grants, to state and local governments, universities, colleges, research institutions, hospitals, other public and private organizations, small businesses, native americans and indian tribes, and minority- and/or women-owned businesses for CDC.
- Plan, direct, and conduct the implementation of pre- and post-award administration and monitoring of assistance awards.
- Provide detailed business management oversight for assistance awards.
- Provide business management technical assistance.
- Maintain a close working relationship with CIOs and other CDC components that use grants and/or cooperative agreements in carrying out their missions.

Figure I-1 shows the relationships between the CIO, GMB, and supporting functions for the Peer Review Process.

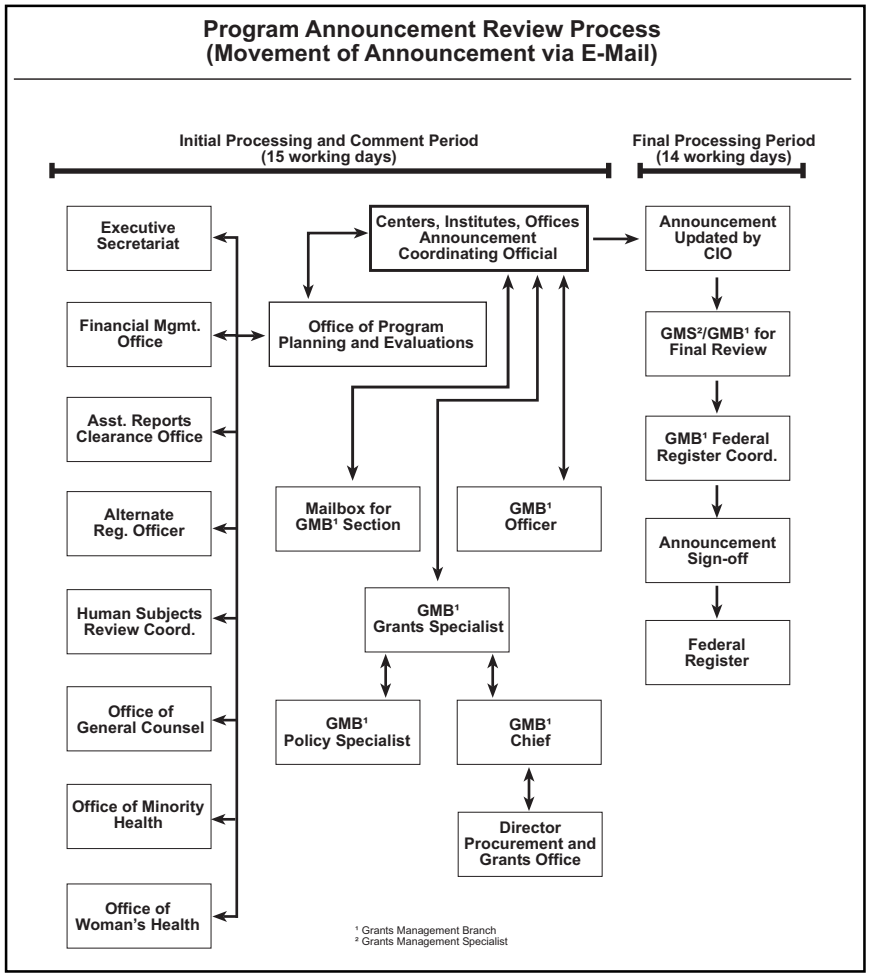

Figure I-1. The relationships between the CIO, GMB, and supporting functions for the Peer Review Process are well defined.

Contracts Management Branch (Atlanta)

The Contracts Management Branch (CMB) is responsible for the acquisition of all supplies and services for the CDC offices in Atlanta, as well as the ATSDR. CMB awards and administers contracts for program-related health studies, professional services, research and development, facility support services, automated data processing equipment and services, equipment, commodities, construction and architectural and engineering services. Procurement methods encompass contracting through sealed bidding, negotiated procurement procedures, simplified acquisition procedures, and established sources. There are various types of contracts written by cmb to include services, construction, research and development, and programmatic. The CMB in Atlanta:

- Plans, directs, and conducts the acquisition of a wide variety of services, research and
- development studies, data collection, equipment, materials, and nonpersonal services in support of research activities, program development, and CDC/ATSDR operations, using a wide variety of contract types and pricing arrangements.
- Contracts for repairs and capital improvements to CDC properties and construction of new buildings.
- Provides leadership, direction, procurement options and approaches in developing specification/statements of work and contract awards.
- Provides training, consultation, and advice to CDC field activities having purchasing authority.
- Participates with top program management in program planning, policy determination, evaluation, and directions concerning acquisition strategies and execution.

CMB Service Sections

- Plan, direct, and conduct the acquisition of non-personal services, research and development, studies, and data collection for CDC/ATSDR through a variety of contractual mechanisms (competitive and non-competitive).
- Perform contract and purchasing administrative activities including coordination and negotiation of contract modifications, reviewing and approving contractor billings, resolving audit findings, and performing close-out/termination activities.
- Assure that contractor's total performance is in accordance with contractual commitments.
- Provide leadership and guidance to CDC/ATSDR project officers and program officials.

CONTRACTS MANAGEMENT BRANCH (Pittsburgh) is responsible for the acquisition of all supplies and services for the NIOSH in Pittsburgh, PA. CMB awards and administers contracts for program-related health studies, professional services, research and development, facility support services, automated data processing equipment, and commodities. Procurement methods encompass contracting through sealed bidding, negotiated procurement procedures, simplified acquisition procedures and established sources. There are various types of contracts written to include services, research and development, and programmatic and range from simplified acquisitions to multi-million dollar contracts.

PROGRAM ACQUISITION BRANCH (PAB) (Washington) is responsible for the acquisition of program related health studies, professional services, and research and development. The Washington PAB office supports the National Center for Health Statistics (NCHS) in Hyattsville, Maryland. The contracts awarded by the PAB are typically services, research and development, and programmatic contracts. Many of the contracts are term type contracts that result in a final deliverable to the Government, while others are for recurring services for a fixed period of time. All competitive procurements are advertised in the Commerce Business Daily (CBD) and copies of solicitation packages may be obtained by sending written requests referencing the solicitation number published in the CBD to Centers for Disease Control and Prevention, 6525 Belcrest Road, Room 1170, Hyattsville, MD 20782,
FAX: (301) 436-3591

CDC SMALL BUSINESS PROGRAM: The Small Business Office is chartered to assist small businesses, minority businesses, and women-owned businesses in their efforts to seek contracting opportunities, in accordance with Federal legislation. Serving as the focal point for information and guidance, the Small Business Office executes the goals and objectives of the DHHS by making opportunities to participate in the agency's procurement activities available. These opportunities to demonstrate capabilities and develop proficiency are generated by examining agency requirements for goods and services and weighing them in comparison to available small businesses that are responsive and responsible. This further requires the Small Business Office to interface with a myriad of business associations, facilitate interagency coordination, and maintain a pool of potential sources. Source development is accomplished by maintaining a Bidder's Mailing List. Due to the competitive nature of contracting, ability to perform is essential. For questions or information on the CDC small business program, send e-mail to ckb9@cdc.gov.

CHAPTER II

RFA Development

CHAPTER CONTENT

ABOUT THE DEFINITIONS

Extramural activities (activities carried out by a source outside the agency) are a principal vehicle for accomplishing the legislatively established mission and goals. CDC may fund extramural activities by using several types of contract instruments for an acquisition relationship, or a grant or cooperative agreement instrument for an assistance relationship. Because the type of instrument to be used is determined by the requirement and purpose of the proposed activity, it is critical to understand clearly the intended purpose of the activity and to recognize the identifying characteristics of each type of relationship. For this purpose, the technical and legal requirements prepared by the PGO are detailed below and provide a brief synopsis of the assistance management process. CDC staff should refer to the CDC Assistance Management Manual for more in-depth information on the complete policy basis and requirements for assistance instruments (currently under development).

DEFINITIONS

1. **Acquisition Relationship** - When the principal purpose is acquisition, by purchase, lease or barter, of property or services for the direct benefit or use of the federal government.

2. **Contract** - A legal instrument that establishes an acquisition relationship between the federal government (the buyer) and a second party (the seller) obligating the seller to furnish personal property or non-personal services (including construction) and the buyer to pay for the product or service provided.

3. **Assistance Relationship** - When the principal purpose is the transfer of money, property, or services to the recipient to accomplish a public purpose of support or stimulation authorized by federal statute. There may or may not be substantial federal involvement during performance of the contemplated activity.

4. **Grant** - The legal instrument that reflects an assistance relationship between the federal government and the recipient in which substantial programmatic involvement is **not** anticipated between the federal agency and the recipient during performance of the contemplated activity.

5. **Cooperative Agreement** - The legal instrument that reflects an assistance relationship between the federal government and the recipient in which substantial programmatic involvement is anticipated by the federal agency in support of the recipient's activities during performance of the contemplated activity.

6. **Substantial Programmatic Involvement** - The provision by CDC CIO staff of collaboration, advice, assistance or coordination with regard to the scientific or technical management of an activity during its performance to a degree beyond normal stewardship responsibilities.

7. **CIO Staff Collaborators** - The CIO staff persons who carry out the responsibilities of substantial programmatic involvement in a cooperative agreement activity.

GENERAL PROCEDURES FOR INITIATION OF NEW EXTRAMURAL ACTIVITIES AND SELECTION OF AWARD INSTRUMENT

1. CIO staff should use existing budget and program planning procedures to propose new extramural activities and mechanisms for awards.

2. CIO staff have an initial responsibility: to weigh the objectives of any new proposed extramural activity against the general objectives of the CIO with regard to its mission; to determine whether the legislative authority exists for acquisition and/or assistance; and, to ascertain the feasibility of implementing the activity. CIO staff should consult very early in the planning with the appropriate Grants Management Officer (GMO) and/or Contracting Officer (CO) to:

    a. Obtain technical advice/guidance with respect to the appropriate award instrument for each project.

    b. Obtain advice and information on the time constraints which will affect the award process.

    c. Determine the appropriate procedures to be carried out to accomplish the acquisition or assistance award.

3. A decision should be made at an early stage of program development (before development of a program announcement or request for contract [RFC]) concerning the appropriate award instrument. CIO and PGO staff may make a recommendation on the appropriate mechanism for a proposed program or activity. For assistance programs, clearance on the proposed use of award mechanism must be obtained through review and approval of a request for authority to use an assistance award (cooperative agreement or grant).

4. The GMO and CO are responsible for ensuring that for each award, the appropriate instrument is used and is consistent with applicable laws, regulations, policies, and procedures.

DISTINGUISHING BETWEEN ACQUISITION AND ASSISTANCE RELATIONSHIPS

1. The initial action is to define the activity or requirement of the program. When an activity or requirement contains elements that are being performed or acquired to fulfill a CDC need for its direct benefit and use, then an acquisition relationship would be used. On the other hand, when financial assistance is being provided to support activities of interest to CDC but of direct benefit to a State, locality or other eligible organization, then an assistance (cooperative agreement or grant) award would be appropriate. In the situations where both acquisition and assistance elements are present, a decision on the use of the proper award instrument will be based on the primary purpose of the action.

2. Characteristics of Acquisition Relationships:

    a. An acquisition relationship exists when CDC plans to acquire by purchase, lease or barter, property, services, or studies (research, training, treatment, prevention, and other programs) for its direct benefit and use. Under an acquisition relationship, a basic arms-length, buyer-seller relationship is established. A contract is used for acquisition. CDC is the purchaser or buyer and establishes requirements or specifications for the needed product or service. CDC also closely monitors the technical and administrative performance and judges acceptability of the product or services against the established requirements or specifications. The Contracting Officer has the right to unilaterally change or redirect the work if CIO developments require a change in direction of the effort, and, if necessary, terminate the contract for convenience or default. Generally, delivery of a product or service is provided by the contractor to the Government.

    b. Contracts normally would be used for such purposes as the following:

        1. Research, surveys, studies, and demonstrations that provide information required by CDC for its direct activities, or for dissemination to the public.

2. Evaluation (including research of an evaluative character) of the performance of CDC programs, projects or grantee activity, when the evaluation is initiated by CDC for its direct benefit or use.

3. Services including security, janitorial, computer, grounds maintenance, snow removal and other government commercial industrial activities.

4. Technical assistance rendered on behalf of CDC to any third party, including those receiving grants or cooperative agreements.

5. Consulting services or professional services of all kinds if provided to CDC or, on behalf of the government, to any third party.

6. Training projects (excluding fellowships) where CDC selects the individuals or specific groups whose members are to be trained, or specifies the content of the curriculum.

7. Planning for CDC use.

8. Production of publications or audiovisual materials required primarily for the conduct of the direct operations of CDC.

9. Design or development of items for CDC use or pursuant to agency definition or specifications.

10. Conferences conducted on behalf of CDC.

11. The generation of management information or other data for CDC use.

12. Construction, architecture and engineering

3. **Characteristics of Assistance Relationships (Grants and Cooperative Agreements)**

a. An assistance relationship exists when CDC awards funds to a recipient to accomplish a public purpose of support or stimulation authorized by federal statute. In such relationships the Government acts as a patron of, or partner with the recipient. Deliverables cannot be a principal purpose of the assistance relationship. The only deliverables are periodic progress reports generally submitted annually.

b. The recipient of a cooperative agreement or grant assumes full responsibility for performance of the project activities and does not serve solely as a conduit for providing funds to a third party. However, the recipient of a cooperative agreement accepts substantial programmatic involvement of CDC staff in scientific or technical assistance of project activities during performance, as agreed upon between the recipient and CDC

before the award. Under an assistance arrangement changes are usually made only as a result of the recipients desire to change the direction of work.

c. Assistance awards are to be used on a program, function, or activity-wide basis for both new and ongoing programs. A program, function, or activity will generally consist of a discrete class of planned independent projects that will be administered separately from other activities, but can be a portion of a defined area of a CIO research program. There may be, however, a single project or recipient for which an award is appropriate and can be justified.

d. Assistance instruments (grants or cooperative agreements) normally are used for purposes such as the following:

   1. General financial assistance (stimulation or support) to eligible recipients under specific legislation authorizing such assistance, e.g. block grants, STD research, education, and demonstration.

   2. Basic and applied research when the principal objective is to stimulate or support development of knowledge to advance the field.

   3. Training projects where the recipient selects the trainees, specifies the plan for training, and uses funds to develop, maintain, and/or enhance their capacity to provide high-quality training.

   4. Planning and delivery of health services at the local, regional, or state level to meet needs identified by the award recipient.

   5. Development and testing of training, prevention, and health service delivery models where the detailed approach is developed principally by the recipient to meet a perceived need in the field.

   6. Conferences to exchange current information, opinion, or findings in an area of CDC program interests for the principal purpose of advancing the field (rather than for the direct benefit of the government).

   7. Demonstration projects.

ASSISTANCE RELATIONSHIPS: DISTINGUISHING BETWEEN GRANTS AN COOPERATIVE AGREEMENTS

1. When it is determined that a financial assistance relationship exists and that CDC has the statutory authority to provide assistance, a decision needs to be made as to whether the grant or the cooperative agreement is the appropriate instrument. Grants and cooperative agreements are distinguished by the degree of federal programmatic involvement anticipated during the performance of the planned activity and the federal purpose of the relationship:

a. The grant must be used when CDC does not anticipate substantial programmatic involvement in the activity by CIO staff during performance of the award.

b. The cooperative agreement must be used when CDC anticipates substantial programmatic involvement in the activity by CIO staff during performance of the award.

2. Substantial programmatic involvement is a relative rather than absolute concept with CDC staff providing guidance, coordination, and/or collaboration with award recipients in programmatic activities to a degree beyond their normal stewardship responsibilities in the administration of grants. The CDC purpose is to support and/or stimulate the recipient's activity by involvement in and otherwise working jointly with the awardee in a partner role, but it is not to assume direction, prime responsibility, or a dominant role in the activity. Examples of substantial programmatic involvement may include:

   a. Collaboration or participation in the design or direction of activities to develop a research protocol, or training or service delivery model.

   b. Coordination, collection, and/or analysis of data from participating sites, (however, data collection for the direct use and benefit of CDC cannot be supported by an assistance award).

   c. Coordination of training of project staff in participating institutions.

   d. When programmatic involvement is necessary, specific CDC staff responsibilities may include:

      - Participation in decision on particular assessment instruments to be used.
      - Providing technical assistance at the recipient's request.
      - Establishing procedures for submission of data to a central source.
      - Participation in the preparation of results for publication.

3. Substantial programmatic involvement does not exist when post-award responsibilities of CDC staff are limited to their normal stewardship, including:

   a. Conducting site visits.

   b. Evaluating progress reports to ensure that the objectives are being accomplished, and terms and conditions of the award are being met.

   c. Deciding whether to proceed from one phase of activity to the next.

   d. Intervening temporarily in unusual circumstances to correct serious deficiencies that develop during a project.

   e. Review of performance after completion.

f. Ensuring compliance with general administrative requirements such as those included in the department's regulation on "Administration of Grants," 45 CFR Part 74 or 92, and E.O. 12372.

4. Cooperative agreement activities must be undertaken only where there is a clear need for agency staff involvement during performance of the project. When the need for substantial programmatic involvement ceases to exist, the program should be changed to a grant program. This should be accomplished on the anniversary date of the award.

5. The desire of CDC personnel to cooperate with an organization or to be involved in a particular activity or project is not a basis for the use of cooperative agreements. The major intent of the program to acquire or provide assistance dictates the selection of the appropriate instrument.

GENERAL COMMENTS ABOUT AWARD INSTRUMENTS

Grants typically support regular research projects, program projects, and research centers. In general, the investigator who applies for a grant, through an eligible institution, is responsible for developing the ideas, concepts, methods, and approach for a research project. In contrast, the awarding center is responsible for establishing the plans, parameters, and detailed requirements for projects that would be supported by contracts. Contracts are usually solicited through requests for proposals (RFPs). In certain circumstances grant applications are invited to support areas of special interest to an awarding center, in which case requests for applications (RFAs) and program announcements (PAs) are issued. RFAs, and PAs are published in the Federal Register. RFPs are published in the Commerce Business Daily. The cooperative agreement, like the grant, is oriented to support or stimulate the recipient's activities, but provides for substantial involvement on the part of the funding agency during the period of performance. Cooperative agreement awards generally derive from applications responding to RFAs or PAs in which other terms and conditions of such involvement are spelled out.

Details of the responsibilities, relationships, and governance of the study to be funded under cooperative agreement(s) are indicated below.

CDC Role:

1. Provide technical assistance, advice and coordination, and assure that CDC guidelines on conflict of interest issues, IRB, etc are followed.

2. Serve as liaison, helping to coordinate activities with awardees. act as a liaison to the CIO, and as an information resource about extramural research activities in the area of specific interest.

3. Attend grantee steering committee meetings as a non-voting technical advisor, assist in developing operating guidelines, quality control procedures, and consistent policies for dealing with recurrent situations that require coordinated action.

1. Serve as liaison between the grantee steering committee and an external monitoring (oversight) group, attending monitoring group meetings in a non-voting role, lending a degree of continuity between monitoring group and steering committee.

2. Assist in the monitoring of field data collection, helping to ensure standardization in methods. and assist in the interpretation and reporting of the collected information.

3. Assist by providing advice in the management and technical performance of the investigation.

4. Assist in promoting the results of grants to the scientific community at large, for use in prevention programs.

Grant applications are classified according to type, such as new, competing continuation (renewal), and supplemental applications, and according to activities, such as regular research projects, conferences, program projects, and centers. The classification of a grant application is indicated by an identification numbering system that appears in the upper right hand corner of the first page of the standard application (Form PHS 398 or PHS 5161). Each part of the identification number has a distinct function. For example: R49CCR403543-01 means the application is assigned to the National Center for Injury Prevention and Control (R49 is a code specifically for the NCIPC), within the Centers for Disease Control and Prevention (CCR - Centers for Disease Control Research). The first two digits of the six digit number determine the region from which the application originated (40 is region four or the lower southeast). The next four digits (3543) are sequential numbers assigned to all applications as they are received. The last two digits (01) show a request for a first year of support.

NEED FOR CAREFUL PLANNING

There are a number of important steps involved in the issuance of an RFA, each of which is essential to its ultimate fate and success.

- **Research agenda with external input:** Each CIO develops research objectives using the best advice it can obtain from either internal or external experts or a variety of types of workshops. Whatever the method, a well developed research agenda and priorities are required as a first step in proceeding with an RFA solicitation for proposals.

- **Development of a realistic time line:** This is a crucial part of the planning process and must take into account the several steps involved from preparing an RFA to the actual award of funds.

- **RFA development and preparation:** This can be accomplished in many ways including the convening of workshops. If the latter is involved, sufficient time should allocated to successfully accomplish this end. In addition, an allowance must be made for the actual writing and internal CIO processing of the RFA document.

- **Sufficient time for applicants to respond to RFA:** It is imperative that a 60 to 90 day time-frame be factored in to allow applicants sufficient time to prepare an application.

- **Sufficient time to obtain approval and advice from the PGO:** To accomplish these requirements, PGO needs are:

- To be involved in up-front discussions of RFA plans.
- To be involved in decisions on award instrument: grant vs cooperative agreement vs contract.
- To be involved in development of RFA or other solicitation language.
- To be involved in establishment of a practical time frame between release of RFA and conduct of pre-award business.

- **Sufficient time for receipt, processing and review of applications:** There are a significant number of steps involved. Time will be required to: process incoming proposals, conduct a staff administrative review for responsiveness, mail applications to reviewers and to allow them time to carry out their assignments, convene peer review panels to conduct merit evaluations of applications and make recommendations, prepare written reports (summary statements) related to each proposal received, and conduct a second level review to conduct programmatic evaluation of applications and make funding recommendations.

- **Sufficient time for PGO to conduct pre-award negotiations and make awards:** Appropriate time must be factored in to properly carry out this task that involves discussions among applicant, GMO, and CIO manager.

The **Time Line** below is intended to be generic and not all encompassing related to activities for each milestone period. This Chapter contains information about program planning and the RFA development process. Chapter III contains information about requirements for initiating SEP procedures and member recruitment. Chapters IV, V and VI provide details about preparing for a SEP meeting, the actual meeting process and the post-meeting activities. Chapter VII provides information about the secondary programmatic review process.

Time Period	Event	Sample List of Activities
June 1 to November 15	Program Planning	Develop Research Agenda Workshops/Advisory Groups Budget Considerations Program Priorities Preparation of Draft RFAs
November 15 to December 15	Discussions with PGO	Award Instrument RFA Wording Determine Correct Templates Finalize RFAs Drafts

Time Period	Event	Sample List of Activities
January 15 to February 15	RFA Approvals	Approval Process for RFAs Finalize RFAs Initiate SEP Procedures Recruitment of Reviewers
February 15 to May 1	Application Preparation Application Receipt Date	Release RFAs Federal Register Notice Applicant Time to Prepare Applications Recruit Members for Programmatic Review Panel
April 1 to June 15	Preparations for Initial Merit Review Meeting Conduct Review Meeting	Responsiveness Check Prepare Reviewer assignment List Prepare Mailing Material for Reviewers Prepare Meeting Agenda Consult with SEP Chair
June 15 to July 15	Preparations for Secondary Programmatic Review Meeting Conduct Meeting	Prepare Summary Statements Prepare Mailing Material Prepare Meeting Agenda Consult with Chair
July 15 to August 1	Prepare Funding Memo Submit to PGO	Document Results of Programmatic Review
August 1 to September 1	Negotiations Notice of Awards	PGO Activities Related to Making Awards

OTHER IMPORTANT CONSIDERATIONS IN RFA DEVELOPMENT

GUIDANCE: On March 2, 1998, Chief, Grants Management Branch, PGO, OPS (E-09), issued the following memo related to a new Program Announcement process; it is reproduced below with only minor editorial modifications:

"The purpose of this memorandum is to provide you with the latest changes for preparing and reviewing CDC and the ATSDR program announcements. The changes identified below are the result of recommendations made by a committee, compromised of representatives from the CDC CIO, ATSDR, and GMB, that was formed for the purpose of streamlining the announcement process."

1. **Revise Section Three of the current *Guide for Preparation of Assistance Requests* (AR Guide).** The guidance for developing a program announcement has been simplified. The announcement itself will be considerably shorter because the administrative requirements of the program are now described in an attachment rather than in the announcement. In addition, the new format should be more user-friendly, providing applicants only the most important information for developing an application.

2. **Begin the program announcement process earlier in the fiscal year so that application processing and review, as well as award procedures, can be carried out according to the DHHS policy requirements.** The CIOs will consult early in the fiscal year (FY) with GMB to determine the correct award instrument to be used for proposed programs and to review and discuss any documentation already prepared that describes the proposed program including recipient and awarding agency activities, etc. (Currently, it is the usual practice to wait until the CIOs receive their fiscal year budgets from the Financial Management Office (FMO) before starting to work on program announcements, thereby leaving inadequate time for the critical review of the applications and the pre-award review by the CIO program officials and GMB of applications and applicant organizations.)

3. **Streamline the review process for program announcements**. When the CIO believes it has a final version of a program announcement, it will simultaneously forward the announcement to GMB and to the Office of Program Planning and Evaluation (OPPE). GMB will review the announcement at the same time it is reviewed by OPPE, FMO, the CDC Legal Advisor, the Office of Minority Health, the Associate Director of Science, etc. Any comments on the announcement will be sent back to the CIO by GMB and OPPE for incorporation into their revised announcement. The revised announcement will be returned to GMB and, if necessary, to OPPE for concurrence. The important change here is that the CIO program officials will assume the responsibility for having the major role in the development and any revisions of their program announcements.

The committee developed a new computer format for preparing the announcements and streamlined procedures for announcement review.

The most pertinent documents for preparing the announcements are to be found on the Grants Management Branch home page http://intranet.cdc.gov/pgo/gmbhome.htm in the menu item called *Grants Issues* followed by *Program Announcements*. The document identified as *Instructions for Developing Program Announcements* provides information and explanation for each announcement section. The next document is *Description of "Other Requirements"* which relates to items that will be identified only by a number and title in the "Other Requirements" section of the announcement. It provides the necessary explanations for the items such as human and animal subjects requirements, HIV/AIDS Program Review Panel requirements, lobbying restrictions, patient care, Executive Order 12372 Review, Public Health System Reporting Requirements, etc. The next document, a *Program Announcement Template*, provides the correct outline for the program announcement and can be downloaded into WordPerfect.

Streamlining of the procedures for announcement review begins when the CIO completes a program announcement. An Announcement Coordinator, designated by the CIO to transmit all announcements, will contact the GMB Grants Management Specialist (GMS) assigned to the program and obtain a program announcement number. After inserting the program announcement number in the announcement, the Coordinator will send the announcement as an e-mail attachment simultaneously to the appropriate Grants Management Officer (GMO), Grants Management Specialist, mailbox address for the GMB section, and to the OPPE Coordinator.

The GMS and the OPPE Coordinator will be responsible for transmitting the announcement via e-mail to those officials from whom they are required to seek review and comment. In making comments on the announcement, reviewers must identify their questions and recommendations by the line number(s) on the left margin of the announcement. The GMS and the OPPE coordinator will each consolidate all comments they receive into an e-mail message back to the CIO Announcement Coordinator. The e-mail message will identify all general comments relating to the announcement first followed by line-specific comments in numerical order. Three weeks (15 working days) are allotted for the OPPE and GMB review of the announcement.

Following the three-week review period, the CIO Announcement Coordinator will then have one week (five working days) to ensure that all offices involved with the announcement review agree upon all the corrections or changes, etc. to the announcement.

When the CIO has updated the announcement and it is ready for publication and/or mailing, the CIO Announcement Coordinator will e-mail the announcement to the GMS, indicating whether the CIO has responded to all the recommendations made by all the reviewing offices. A copy of the e-mail message from OPPE, containing all the reviewer comments received through OPPE, will accompany the announcement so that the GMS can see what other changes were recommended by other reviewing officials. At this same time the CIO must provide to the GMS a "certified" signed document of available program funds.

For those announcements that must be published in the *Federal Register*, the Grants Management Branch will be responsible for submission to the *Federal Register*.

The GMS will develop an attachment to the Program Announcement that will consist of the explanations of all the "Other Requirements" identified by number and title only in the program announcement. The attachment will accompany the announcement on the INTERNET and in the application kit.

TEMPLATES AND APPLICATION FORMS:

Templates for RFA announcements are detailed in Appendix I and can be used to simplify their preparation. In addition, the following helpful information can be used as a guide to development of RFA documents.

PROGRAM REQUIREMENTS (YOU CAN INSERT YOUR SPECIFIC PROGRAM REQUIREMENTS HERE—THESE ARE EXAMPLES)

The following are applicant program requirements:

A. A principal investigator who has conducted research, published the findings in peer-reviewed journals, and has specific authority and responsibility to carry out the proposed project.
B. Demonstrated experience (on the applicant's project team) in conducting, evaluating, and publishing in peer-reviewed journals **(INSERT AREA of RESEARCH)** (as previously defined).

C. Effective and well-defined working relationships within the performing organization and with outside entities that will ensure implementation of the proposed activities.
D. The ability to carry out a **(INSERT AREA of RESEARCH)** project as previously defined under Background and Definitions.
E. The overall match between the applicant's proposed theme and research objectives and the program priorities as described under the heading "Programmatic Priorities."

Note: Grant funds will not be made available to support the provision of direct care services. Eligible applicants may enter into contracts, including consortia agreements (as set forth in the PHS Grants Policy Statement) as necessary to meet the requirements of the program and strengthen the overall application.

APPLICATION CONTENT

Applications should include:

A. The project's focus that justifies the research needs and describes the scientific basis for the research, the expected outcome, and the relevance of the findings to reduce morbidity, mortality, disability, and economic losses. This focus should be based on recommendations in Healthy People 2000;**(add other priority documents here)**.
B. Specific, measurable, and time-framed objectives.
C. A detailed plan describing the methods by which the objectives will be achieved, including their sequence. A comprehensive evaluation plan is an essential component of the application.
D. A description of the principal investigator's role and responsibilities.
E. A description of all the project staff regardless of their funding source. It should include their title, qualifications, experience, percentage of time each will devote to the project, as well as that portion of their salary to be paid by the grant.
F. A description of those activities related to, but not supported by the grant.
G. A description of the involvement of other entities that will relate to the proposed project, if applicable. It should include commitments of support and a clear statement of their roles.
H. A detailed first year's budget for the grant with future annual projections, if relevant. Awards will be made for project periods of up to three years.

An applicant organization has the option of having specific salary and fringe benefit amounts for individuals omitted from the copies of the application that are made available to outside reviewing groups. To exercise this option: on the original and five copies of the application, the applicant must use asterisks to indicate those individuals for whom salaries and fringe benefits are not shown; the subtotals must still be shown. In addition, the applicant must submit an additional copy of page four of Form PHS-398, completed in full, with the salary and fringe amounts shown. This budget page will be reserved for internal staff use only.

EVALUATION CRITERIA

Upon receipt, applications will be reviewed by CDC staff for completeness and responsiveness to Program Requirements (see page II-12 for an example of requirements).

Incomplete applications and applications that are not responsive will be returned to the applicant without further consideration. Applications that are complete and responsive may be subjected to a preliminary triage on streamlined review by a peer review group to determine if the application is of sufficient technical and scientific merit to warrant further review. Applications judged to be noncompetitive will be withdrawn from further consideration and CDC will promptly notify the principal investigator/program director and the official signing for the applicant organization. Those applications judged to be competitive will be further evaluated by a dual review process based on a prescribed set of evaluation criteria designed to fit the solicitation. (**Criteria for each level of review will be provided at this time.**)

Awards will be made based on priority score ranking by the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) or a chartered extramural merit review group, programmatic priorities and needs as determined by the (**INSERT NAME OF SECONDARY REVIEW GROUP HERE**), and the availability of funds.

WHAT NEXT?

After the RFA is completed, approved, and released to the community, preparations must be made for a variety of activities related to the arrival of applications. A major consideration is the process used to evaluate their scientific merit and programmatic importance so that the wisest investment of funds can be assured to accomplish the objectives of the RFA. The next several chapters will be devoted to describing the underlying rationale, requirements, and details for conducting a peer review process that has served biomedical, behavioral, and social research well since its administrative "invention" some 50 years ago.

REFERENCES

The Federal Grant and Cooperative Agreement Act (Act) of 1977, as amended (31 U.S.C. 6301-08).

HHS Grants Administration Regulations, 45 CFR 74 and 92 and HHS policy (Grants Policy Directive (GPD) 2.02).

3. Selection of Award Instrument: Prepared By Office of Program Support, Procurement and Grants Office, October, 1993.

4. Sample RFA Templates, Appendix I**.**

CHAPTER III
Peer Review Process Overview

CHAPTER CONTENT

Peer Review

Peer Review is a process that includes an independent assessment of the technical or scientific merit of research by peers who are scientists with knowledge and expertise equal to that of the researchers whose work they review and who provide written assurance that their reviews are free of any real or perceived conflicts of interest.

Because of the magnitude, diversity, and complexity of its research mission, as well as its pursuit of excellence, the CDC draws for assistance on the national pool of scientists and other subject matter experts actively engaged in research. These scientists assist the CDC by advising on the selection of the most meritorious and the most promising research projects for award.

The Peer Review Process follows a consistent series of events, from publishing the initial Requst for Applications (RFA) to funding approval (see Figure III-1).

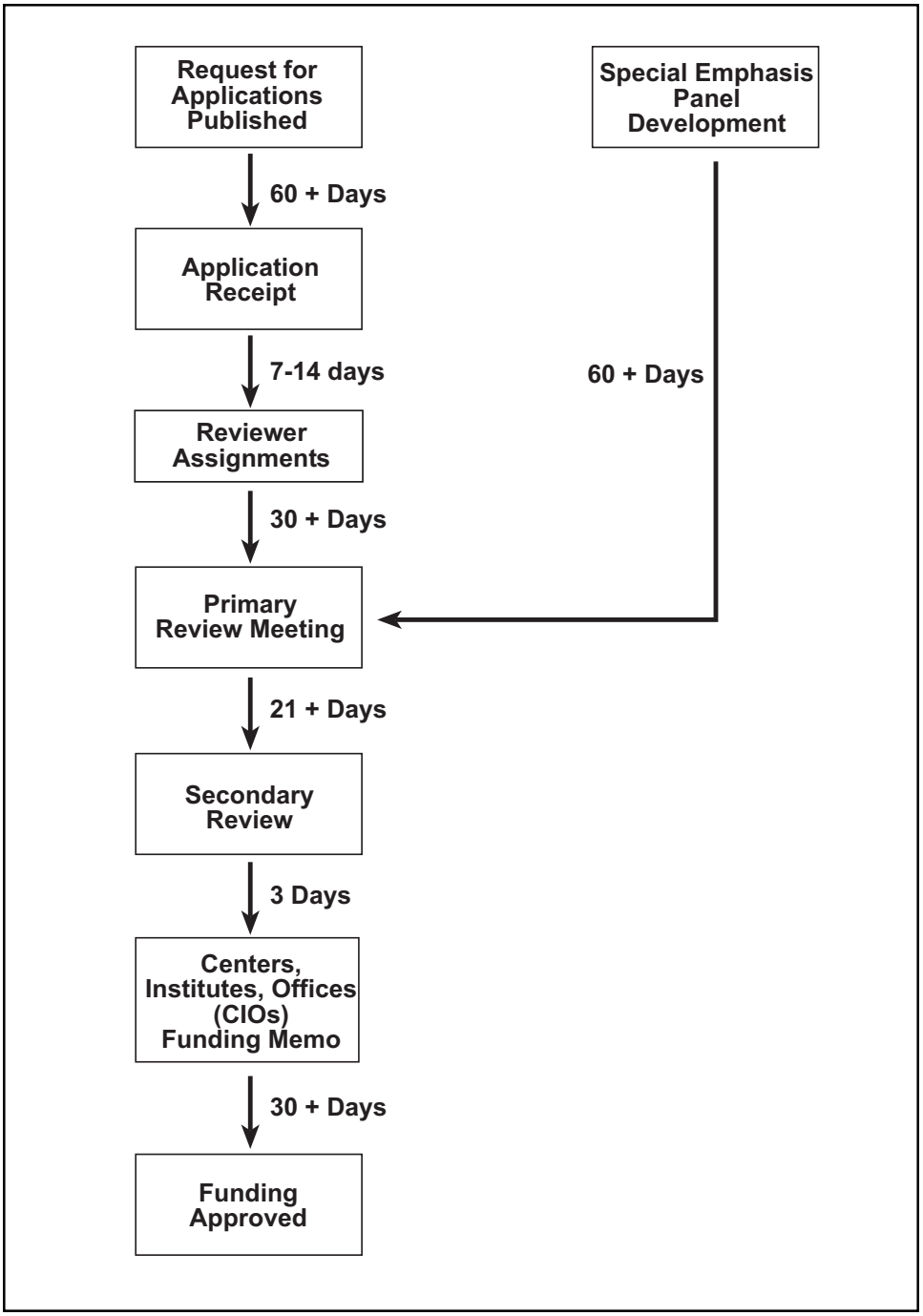

Figure III-1. Sequence of events for the Peer Review Process

Dual Review of Grant Applications

The peer review system for grant applications and cooperative agreements, encouraged and used by the CDC, is based on two sequential levels of review, referred to as the "dual review system":

1. Level I: Scientific merit review based on published evaluation criteria.

2. Level II: Programmatic review based on the results of the merit review and programmatic considerations.

The first level involves panels of experts organized according to scientific disciplines or specialty research areas for the primary purpose of evaluating the scientific and technical merit of grant and cooperative agreement applications. These panels are generally referred to as peer review panels. There are two types:

1. External Merit Review Groups: In the National Institute of Occupational Safety and Health (NIOSH) and the National Center for Injury Prevention and Control (NCIPC), these are chartered, permanently functioning committees that meet regularly specifically for grant application peer review.
2. Special Emphasis Panels (SEPs): These are peer review panels convened on a one-time, ad hoc basis depending on CIO need and covered by one CDC umbrella charter (see below). For more information on SEPs, see the Committee Management Web Site (http://intranet.cdc.gov/maso/cmppa/cmppa.htm).

The second level of review involves a separate senior advisory panel whose primary purpose is to factor in the scientific and technical merit results from the first level of review, important programmatic considerations such as program priorities, program relevance, portfolio balance, geographic considerations, budgetary considerations, and other criteria germane to the particular announcement and CIO. There are two types of secondary review panels:

1. Chartered Federal Advisory Committees: The NCIPC has established the Secretary's Advisory Committee for Injury Prevention and Control (ACIPC)that is composed of both scientific and lay representatives from the scientific community who are noted for their expertise, interest, or activity in matters related to the mission of the NCIPC.

2. Senior CDC Staff Advisory Committees: These are ad hoc programmatic review committees convened as needed to perform the programmatic review functions previously mentioned.

The dual review system, which separates the scientific assessment of proposed projects from policy decisions about scientific areas to be supported and the level of resources to be allocated, permits a more comprehensive, objective evaluation than would result from a single level of review. The dual system of review provides responsible CDC officials with the best available advice about scientific as well as programmatic issues and funding priorities.

A more detailed discussion of several important procedural facets of the peer review process, particularly the SEP process, is provided below that contains principles that are common to the review of all grant applications and cooperative agreements submitted to the CDC.

Level I: Scientific and Technical Merit Review

The increased number of assistance awards from CDC/ATSDR and liberalized eligibility criteria have resulted in a dramatic increase in the number of competitive applications. Subsequently, CDC and ATSDR are under increased scrutiny from applicant organizations, their supporters, and other interested parties. Among health department applicants, there is greater competition for available resources as the emphasis on application quality (a major factor in determination of awards funding) increases.

Special Emphasis Panel

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP) provides the most practical, economical and objective method of application review by including federal and private sector experts. The integrity of the review process, the ability to award and process grants in a timely manner, and CDC/ATSDR responsiveness to applicants is facilitated by the panel.

The SEP is an alternative form of the objective review process, enabling expert review of assistance applications, and providing non-federal members a decision-making role. Requirements for SEP composition ensure a balance of representation, providing additional objectivity to the process. **All CDC/ATSDR programs that award grants or enter into cooperative agreements may use this panel for the review of these assistance applications.**

SEP Membership

There are no standing or appointed members of the SEP, and regulations prohibit establishment of subcommittees to the SEP. If more than one panel is required for a particular review, each is established as a separate SEP. The SEP has a fluid membership, with members designated to serve for individual meetings rather than being formally appointed for fixed terms of service. Individuals designated to serve for a specific review meeting will be, upon active participation, members of the SEP for that meeting only. Thus, SEP membership changes with each meeting, and several meetings may convene concurrently.

The SEP is not considered a substitute for chartered committees with appointed members serving fixed terms.

Federal Advisory Committee Act

CDC has chartered the Special Emphasis Panel in accordance with the Federal Advisory Committee Act (FACA). CDC's Committee Management and Program Panels Activity (CMPPA) tracks its membership and provides recurring and special reports to the Department. The FACA also requires publication of a Notice of Meeting in the *Federal Register* at least 15 days before each individual SEP meeting, and compilation of minutes for each SEP meeting.

SEP Charter Renewal

The Disease, Disability and Injury Prevention and Control Special Emphasis Panel's initial charter was prepared by CDC and signed by the Secretary, DHHS, on September 18, 1994. Approximate annual costs and an estimated number of reviewers were included, as well as a standard Financial Operating Plan. The charter will be forwarded to the Secretary by the CMPPA, for renewal at appropriate two-year intervals. The latest charter renewal was approved on September 14, 2000. A copy of the Charter is provided at the end of this chapter as Exhibit III-1, page III-13.

Delegations of Authority
The following is a list of the delegations of authority in effect for Special Emphasis Panels.

- Delegation of Authority to Designate Chairs and Invite Members to Serve on the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel. Dated and signed on October 26, 1994, by the Assistant Secretary for Health, delegating authority to the Director, Centers for Disease Control and Prevention, and the Administrator, Agency for Toxic Substances and Disease Registry.

- Delegation of Authority under the Federal Advisory Committee Act to make determinations that advisory committee meetings or portions thereof may be closed to the public. Signed and dated on February 16, 1995, by the Director, Centers for Disease Control and Prevention, delegating authority to the Associate Director for Program Support (formerly Associate Director for Management and Operations), CDC.

- Delegation of Authority to Sign Federal Register Notices. Signed and dated March 21, 1998, by the Director, Centers for Disease Control and Prevention, delegating authority to: Deputy Administrator, ATSDR; Director, Office of Policy and External Affairs, ATSDR; Deputy Director, CDC; Associate Director for CDC/Washington; Associate Director for Program Support (formerly Associate Director for Management and Operations), CDC; Director, Executive Secretariat; Director, NIOSH; Director, MASO; and Director, PGO.

Appointment of Members

This process should be initiated 60 days before actual recruitment. CIOs are encouraged to invite individuals who have not served on a panel in a given year, however, if their expertise is required, members may serve on more than one SEP in a period of one year.

Following the guidelines for member selection, the Designated Federal Official (DFO) will:

- Prepare the MEMO: Request to Appoint Members to Special Emphasis Panel—Action, and secure the signature/approval of the CIO Director. An example of the SEF memo is shown in Exhibit III-2, page III-16.

- Submit the signed memo to the CMPPA.

The CMPPA will:

- Verify that all nominees are eligible to serve on a Federal Advisory Committee by reviewing the list of persons determined ineligible by the Office of Research Integrity.

- Determine if nominees can receive a waiver from HHS policy. These waivers are required if more than one person from the same institution is requested to serve on a SEP or if the same person is requested to serve simultaneously on two CDC committees.

- Forward the MEMO: Request to Appoint Members to Special Emphasis Panel—Action for approval to the Director.

- Notify the DFO immediately upon receipt of the approved MEMO so the DFO can begin to initiate communications with the appointed panel members.

A waiver from HHS policy is required if more than one person from the same institution is requested to serve on a SEP or if the same person is requested to serve simultaneously on two CDC committees.Examples of each of these types of waivers are shown in Exhibits III-3 and III-4, page III-18 and III-20.

Communication/Correspondence with Potential Reviewers

Prior to Inviting a Reviewer

The DFO will:

- Pre-select and contact potential reviewers to establish availability.

- Discuss confidentiality and potential conflict of interest with potential reviewers.

The DFO should inform potential reviewers that formal appointments will have to be approved by the Director, CDC.

Following Appointment of Members and Designation of a Chairperson, the DFO will provide panel appointees with:

- The list of applications/proposals.

- Conflict of Interest and Confidentiality Certification documents (CDC 0.1215A).

(If conflicts are discovered concerning a grant application(s), a reviewer *will not* be disqualified. However, that reviewer may not participate in the review of the application(s) in conflict.)

If no disqualifying conflict is discovered, potential reviewers will:

- Promptly return the signed certification to the Committee Management and Program Panels Activity (CMPPA) with the prepared FedEx label provided by the DFO.

When the number of applications is small (e.g., six or less), or reviewers will participate in a site visit or teleconference, the DFO may verbally describe the application(s) to be reviewed. In such cases, the DFO will:

- Provide application number, title, principal investigator's name, applicant institution's name.

- Ask potential reviewers if any real or apparent conflict of interest exists.

Written Correspondence to Appointed Reviewers

First Mailing Checklist

The DFO will send:

- The transmittal letter.
- A list of applications/proposals to be reviewed.
- The Conflict of Interest and Confidentiality Certification (CDC 0.1215A) **(Must be signed and returned before applications may be sent to the reviewer).***
- A Reviewer's Guide to the Special Emphasis Panel Process (see Appendix II).
- An overnight delivery service return shipping label.

Second Mailing Checklist

The DFO will send:

- The transmittal letter
- Agenda, Roster, and Reviewer Assignment Sheets
- Logistics information for reviewers
- Applications

*Completed Conflict of Interest and Confidentiality Certifications (Form B below) should be sent by overnight delivery service to:

Committee Management and Program Panels Activity, MASO
Attn: SEP
Centers for Disease Control and Prevention
4 Executive Park Drive, Room 1117
Atlanta, GA 30329

CONFLICT OF INTEREST AND CONFIDENTIALITY FORMS

Several forms are used to ensure that a conflict of interest does not exist:

- Background information explaining conflict of interest to reviewers (evaluators).

- Conflict of Interest and Confidentiality Certification for Individuals Evaluating Proposals, Applications or Active Projects. Reviewers are asked to certify by signature that they will avoid conflicts with any organizations or applicants to which technical assistance may have been offered.

- Certification Regarding Confidentiality of Information. Reviewers are asked to certify by signature that confidentiality will be maintained.

- The Conflict of Interest and Confidentiality of Information form is given to reviewers in the meeting room. Reviewers sign and indicate that they were not involved in the review of any application that may have represented a conflict. Examples of these forms are provided as Exhibits III-5 through III-8, pages III-21-III-24.

Determination to Close

Due to the confidential nature of some aspects of Panel meetings, including personal and/or proprietary information, the application review portions of all Special Emphasis Panel meetings are closed to the public. The authority to close a CDC/ATSDR meeting is delegated to the Associate Director for Program Support, CDC, under provisions of the Government in the Sunshine Act.

The DFO:

- Prepares the MEMO: Determination to Close and Agenda, securing the signature/approval of the CIO director. A sample of this memo is shown in Exhibit III-9, page III-25.

- Submits the signed memo and agenda to the CMPPA.

The CMPPA:

- Secures Office of General Counsel clearance.

- Forwards the Memo, Determination, and Agenda to the Associate Management and Operations, CDC, for approval and signature. A sample of this memo is shown in Exhibit III-10, page III-26.

Meeting Arrangements

Upon determining the suitability of using the SEP, the DFO will make arrangements for:

- Meeting Place
- Dates and Times
- All travel arrangements and cost of travel are the responsibility of the DFO and CIO. (See Member Reimbursements)

  Note: A site visit or reverse site visit may be conducted as a preliminary meeting to the SEP, to provide expert consultation or advice to the SEP. (Any number of the panel members may participate in site visits and reverse site visits.)

After initial arrangements are made, the DFO will forward the following documents to the CMPPA:

1. Memo: *Determination to Close a Meeting and agenda* (CMPPA reviews the document and forwards through the Office of General Counsel and the Associate Director for Management and Operations, CDC, for clearance and approval). (See Determination to Close.)

2. Completed *"Information to Advertise Meeting of SEP in the Federal Register"* sheet (CMPPA prepares the Federal Register notice, obtains appropriate approvals and signatures and forwards to the Federal Register for publication). (See Notice of Meeting.)

3. Memo: *Request to Appoint Members to SEP* (a Professional Area Breakdown will accompany this document). (See Appointment of Members.)

Meeting

The Federal Advisory Committee Act requires that a DFO be present at all meetings of a chartered committee.

The DFO will:

- Call meeting
- Approve agenda
- Designate chair
- Adjourn meeting
- Prepare minutes for certification by chair

The DFO checklist for the review meeting includes the following items:

- List of grant applications to be reviewed.
- Provide instructions about confidentiality and conflict of interest.
- Obtain each member's signature on the "Conflict of Interest and Confidentiality of Information Certification" (CDC 0.1215B) at the beginning of the meeting.
- Provide Script to Panel Chairperson.

Minutes

It is the duty of the DFO to ensure that detailed minutes are kept. Minutes will contain:

- Dates and times of meeting
- Location of meeting
- Membership roster
- Signatures of Panel Chairperson and DFO, certifying accuracy
- Total number and types of grants reviewed
- Total dollars requested
- Total number of applications and dollar amounts favorably recommended
- Total number of applications and dollar amounts not recommended for further consideration
- Total number of applications and dollar amounts recommended for deferral

The original signed minutes will be filed in the official meeting file in the CMPPA. The minutes and roster are due within 14 calendar days following the review. A sample of the meeting minutes is shown in Exhibit III-11, page III-27.

Roster

A roster of all members who served on the panel must be submitted for each SEP meeting and should be attached to the meeting minutes. The CMPPA will enter the information from the roster into a database of SEP members. Sample roster is shown in Exhibit III-12, page III-28.

Official File

The Official File for all SEP meetings will be maintained by the Committee Management Program Panels Activity (CMPPA), MASO.

The Official File Checklist includes the following items:

- *Federal Register* Notice
- Conflict of Interest Forms Originals (Signed prior to SEP meeting)
- Conflict of Interest and Confidentiality of Information (Signed at the SEP Meeting)
- Meeting Roster
- Agenda (for public distribution)
- Accounting Information
- Minutes of Meeting

Member Reimbursements

- Travel for SEP members will be processed and reimbursed by the program office using the SEP.
- Members outside the federal government will be paid at the rate of $250 per day.
- Twenty-one calendar days prior to the meeting, the DFO will submit a requisition through the appropriate Administrative Office for a purchase order for reimbursement of panel members* for professional services.

*List the name, address, and Social Security Number of each panel member to be reimbursed at the $250 daily rate.

Justification

Professional Services. The vendors (the individuals indicated in the above list) shall provide oral and written comments and recommendations at the **(NAME OF SEP)**.

_____

To be held (date)_____ at (location of SEP)

_____

LEVEL II: Programmatic Review

A second level of review will be conducted by a chartered committee or a panel of senior federal officials. These advisory committees will review the ranked proposals to assure maximal impact and balance of the proposed research. Examples of the factors to be considered will include:

a. The results of the peer review.
b. The extent to which the proposed research addresses program needs and priorities.
c. National needs.
d. Budgetary considerations.
e. Other

A more thorough presentation of the details involved in the secondary review is provided in Chapter VII.

Separation of Program and Review Responsibilities of CDC Staff

To further ensure the objectivity and credibility of the peer review process, staff responsibilities are different and well defined as is the case with the chartered external merit review groups in NIOSH and NCIPC. The review, program, and grants and contract management staff of the CDC have important but separate responsibilities in the review, award, and management of grants.

Review Staff

- Coordinate the charter and member nomination process
- Select ad hoc reviewers
- Provide orientation for members
- Explain and interpret CDC review policies and procedures
- Determine responsiveness of grant applications to program announcement
- Assign review responsibilities to panel members
- Manage project site visits
- Manage meetings
- Serve as Designated Federal Official (DFO)
- Prepare summary statements
- Attend secondary advisory committee meetings to provide requested information in support of peer review recommendations
- Communicate with program staff on review
- Discuss review questions with applicants

Program Staff

- Develop program initiatives
- Provide guidance and assistance to applicants
- Interpret program policy and guidelines for reviewers
- Attend peer review meetings as program resource person(s)
- Present peer review recommendations to secondary advisory committees
- Discuss review questions with applicants
- Manage output of grants (dissemination)
- Evaluate programs
- Communicate with review staff on program matters
- Monitor research progress during the award period

Grants and Contracts Management Staff

- Provide business guidance to applicants and reviewers as necessary
- Participate with program staff in budget negotiations prior to and following awards
- Attend peer review meetings as resource person(s)
- Maintain official grant and contract files
- Provide fiscal management of grants and contracts

Exhibit III-1

Charter

DISEASE, DISABILITY, AND INJURY PREVENTION AND CONTROL
SPECIAL EMPHASIS PANEL

Purpose

The Secretary of Health and Human Services is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) to make grants-in-aid for research projects relating to health. In addition, the Secretary is authorized under Sections 306, 308, 317, 317a, 318, 391, 1501, 1701, and 1706 of the Public Health Service Act (42 U.S.C. 242k, 242m, 247b, 247b-1, 247c, 280b, 300k, 300u, 300u-5); Section 104(I) of the Comprehensive Environmental Response,
Compensation, and Liability Act (42 U.S.C. 9604(I)); and other authorities as appropriate to support grants, cooperative agreements, and studies relating to the prevention and control of diseases, disabilities, injuries, and impairments of public health significance.

This panel will review applications and proposals for research projects and for grants and cooperative agreements in the areas of the causes, prevention, and control of diseases, disabilities, injuries, and impairments of public health significance; exposure to hazardous substances in the environment; health promotion and education; and other
related activities that promote health and well-being.

Authority

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Panel is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel shall provide advice and guidance to the Secretary; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; and the Administrator, Agency for Toxic Substances and Disease Registry, regarding the scientific and technical merit of grant and cooperative agreement assistance applications relating to the causes, prevention, and control of diseases, disabilities, injuries, and impairments of public health significance; exposure to hazardous substances in the
environment; health promotion and education; and other related activities that promote health and well-being.

Structure

Members and Chairs shall be selected by the Secretary, or other official to whom the authority has been delegated, on an "as needed" basis in response to specific applications to be reviewed. The Panel will consist of approximately 460 members, of whom approximately 210 may be voting ex officio members. Members will be selected from authorities in the various fields of prevention and control of diseases, disabilities, and injuries. Members of other chartered
Department of Health and Human Services' advisory committees may serve on the Panel if their expertise is required.

Management and support services shall be provided by the Committee Management and Program Panels Activity, Centers for Disease Control and Prevention.

Meetings

Meetings shall be held as necessary (approximately 30 times per year) as determined by the Designated Federal Official, who shall also approve the agenda. A government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of $250 per day, plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the Panel, including compensation and travel expenses for members but excluding staff support, is $631,618. Estimate of annual person-years of staff support required is 2.1 at an estimated annual cost of $120,622.

Reports

In the event a portion of a meeting is closed to the public, a report shall be prepared annually which shall contain, at a minimum, a list of members and their business addresses; the Committee's functions, dates and places of meetings; and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department's Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel will terminate on September 18, 2002.

APPROVED:

(signed and dated September 14, 2000, by the Director, Centers for Disease Control and Prevention)

Exhibit III-2

Sample "Request to Appoint Members to the Special Emphasis Panel"
(Date)

Director, CIO

Request to Appoint Members to Special Emphasis Panel — ACTION

Director, CDC

ISSUE

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for **(INSERT NAME OF SOLICITATION)** Program Announcement **(INSERT NUMBER)**, will hold a meeting on **(INSERT DATE)**, to review, discuss, and evaluate applications received in response to Program Announcement **(INSERT NUMBER)**. The applications being reviewed include information that requires the expert evaluation of infectious disease specialists, health educators, community representatives, and behavioral scientists.

DISCUSSION

The nominees listed below possess the necessary expertise and represent a geographic, demographic, and gender balance. If all nominees are approved, female and minority representation would be as follows:

Female: % (# of ## nominees)
Minority: % (# of ## nominees)
% Black
% Hispanic
% Asian/Pacific Islander
% American Indian/Alaska Native
Public Representation: %
State/County/Local Representation: %
Federal Representation: %

Geographic Breakdown:
West %
Central %
East %
South %

NOMINEES
(list names in alphabetical order)

RECOMMENDATION

It is recommended that the above list of proposed reviewers be formally appointed to serve on the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Cooperative agreements for **(INSERT NAME of ANNOUNCEMENT)** Program Announcement **(INSERT NUMBER)**.

DECISION

Approved _____ Date _____

Disapproved _____ Date _____

Signature, CIO Director
Attachment:

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel Meeting:

Cooperative Agreements for **(INSERT NAME OF ANNOUNCEMENT)** Program Announcement **(INSERT NUMBER).**

Professional Area Breakdown: For each name* indicate Race, Gender, Organization Type**, Experience and State.

* Indicate proposed Chair

** Designate "type" of organization - i.e., Federal/State/County/Local Government, Public (private industry).

REFERENCE INFORMATION: ACRONYM PREFERENCE

Race and National Origin Identification:
A/PI - Asian/Pacific Islander
AI/AN - American Indian/Alaska Native
B - Black
H - Hispanic
W - White

Gender Identification:
F - Female
M - Male

Exhibit III-3

SAMPLE DEPARTMENT WAIVERS

Date

Director, CIO

Request to Waive Department Policy Regarding Two Committee Members from the Same Organization in the Same City

Director, CDC

I am requesting exceptions be made to Department Policy to allow **(INSERT NAME ONE, INSERT NAME TWO, etc.)** to serve on the CDC, **(INSERT NAME)** Special Emphasis Panel (SEP): Cooperative Agreements for **(INSERT NAME)**. Inclusion of these three persons would mean there would be two persons each from three different institutions on this SEP. This Panel will convene on **(INSERT DATE)** to review applications undergoing competitive review for award in **(INSERT YEAR)**.

An extensive search was made to obtain qualified candidates for this panel with education and expertise in rural public health, occupational safety and health in agriculture, agricultural engineering, Cooperative Extension, small minority farmers, evaluation of interventions, agricultural education, and stress, and who are available and willing to dedicate time to this review. Finding qualified persons able to serve was further complicated because many of those with the expertise to serve could not because they are submitting an application themselves. The individuals discussed here have backgrounds in various areas related to the expertise needed on this panel.

Both Jane Doe, Ph.D., M.P.H., and Thomas Black, Ph.D., who is also a proposed nominee for this panel, are from Samson University. Dr. Doe is Associate Professor in the School of Public Health and is highly recognized for her expertise in public health and in stress. Dr. Black is an agricultural safety engineer and Extension Safety Leader in the Food, Agriculture, and Biological Engineering Department with strong expertise in agricultural safety, agriculture education, and cooperative extension.

Both Mary Smith, R.N., Ed., and George Brown, Ph.D., who is also a proposed nominee for this panel, are African Americans from All State University. Dr. Smith is Dean of the School of Nursing and has expertise in rural health, education, and community-based agricultural health projects. Dr. Brown is Associate Professor of Agricultural Education with expertise in agricultural education, cooperative extension, evaluation and problem solving in education, and priorities of small farmers.

Both Ann Chin, Ph.D., and Edna White, Ph.D., who is also a proposed nominee for this panel, are from Star State University. Dr. Chin is Asian and in the Department of Chemical and Bioresource Engineering. Her expertise is related to tractor safety. Whereas Dr. White is Director of the Injury Control Research Center and has expertise in injury control and evaluation.

In view of the foregoing, it is requested that you grant this waiver for the service of all six of these individuals on the SEP to he held in response to Program Announcement **(INSERT NUMBER)**.

Signature, Director, CIO

Approved:_____ Date: _____

Disapproved: _____ Date: _____

Signature, Director, CDC Date

Date

Director, CIO

Exhibit III-4

Request for Waiver of Department Policy Regarding Service on Two Committees Concurrently

Director, Centers for Disease Control and Prevention

I am requesting that an exception be made to Department Policy to allow Linda Cortez, R.N., Ph.D., to serve on the CDC Disease, Disability and Injury Prevention and Control Special Emphasis Panel (SEP): **(INSERT NAME of PANEL)**. This Panel will convene on **(INSERT DATE)** to objectively review training grants undergoing competitive review for award in 2000. Dr. Cortez is currently serving on the **(INSERT NAME OF COMMITTEE)** for a term that began **(INSERT DATE)** and ends **(INSERT DATE)**.

An extensive search was made to obtain qualified candidates for this panel with education and expertise in occupational health and safety, health and cultural issues for Hispanic workers, with experience in reviewing competitive grants and who are available and willing to dedicate time to this review. Dr. Cortez is a registered nurse and nurse practitioner with an extensive research and publication record that includes cultural and health issues related to the Hispanic community. She is currently chairperson of a department of psychiatric and community health nursing as well as acting chair for maternal & child health. This experience will be particularly valuable in reviewing the wide diversity of cooperative agreements dealing with community-based intervention research which are expected to include Hispanic workers and children.
In view of the foregoing, it is requested that you grant this waiver allowing Dr. Cortez to be appointed to serve on the Special Emphasis Panel to be held **(INSERT DATE)**.
Signature, Director, CIO

Approved:_____ Date: _____

Disapproved: _____ Date: _____

Director, CDC Date

Example III-5

Conflict of Interest Statement: Information for Evaluators

Please note that federal statutes and regulations concerning conflict of interest carry criminal penalties for violation. You are personally responsible for identifying any such conflict of interest situations arising in connection with a grant or cooperative agreement application, proposal, or active project that you are asked to evaluate as a member of any review group.

In the case of a grant or cooperative agreement application being evaluated at the same time as other proposals, if you have a conflict with a single application, or with a noncompetitive proposal, you must recuse yourself from portions of the meeting during which that particular application or proposal is to be evaluated.

After reading this document, please list on the Conflict of Interest and Confidentiality Certification any applications or proposals with which you have a conflict of interest, whether real or apparent.

The following guidance is provided to assist you in determining whether, in fact, you are faced with a real or apparent conflict of interest. The guidance is not all-inclusive due to the nature of conflict of interest subject matter.

1. No individual may evaluate an application or proposal or evaluate an ongoing project from an organization in which:

    - The evaluator, his/her spouse, minor child, or partner has a financial interest.

    - The evaluator has a close professional, scientific, or personal relationship. Such relationships might include faculty affiliation, officer, director, member, owner, trustee, expert advisor, consultant (with or without compensation) employee, family member, or friend.

    - The evaluator is negotiating or has an arrangement of prospective employment.

2. An individual should avoid any action that might give the appearance that a conflict of interest exists or could reasonably be viewed as affecting the evaluator's objectivity. For example, an evaluator should not participate in the deliberations and actions on any applications from a recent student, a recent teacher, a professional collaborator with whom the evaluator has worked closely, a close personal friend, or a scientist with whom the evaluator has had long-standing scientific or personal differences.

Exhibit III-6

Conflict of Interest and Confidentiality Certification

[Sample of "Conflict of Interest and Confidentiality of Information Certification"]

I will avoid conflicts of interest by absenting myself from evaluations and discussions of applications, proposals, and projects involving any organization:*

1. Where, to the best of my knowledge and belief, I or my spouse, minor child, or partner have a financial interest.

2. Where I am an officer, director, trustee, partner, consultant, or employee or otherwise similarly associated.

3. Where there exists any arrangement concerning my prospective employment, financial interest, or other similar association.

4. Where I have provided technical assistance to the applicant in the preparation of their application or any other closely related CDC funded project.

5. Where I will serve as a project officer for the project.

6. Where I am a supervisor of anyone who is subject to one of the above mentioned items.

I will also avoid any actions that might give the appearance that a conflict of interest exists or could reasonably be viewed as affecting my objectivity.

*The term "organization" includes the entire system in which you are an employee, consultant, officer, director, or trustee or have a financial interest.

Name and Date of Review: _____

I have indicated, below, all organizations with which I am connected/have financial interests which relate directly or indirectly to this review.

_____
_____
_____
_____
_____

My signature is a confirmation that the Certification Statement detailed herein is accurate and true, and is consistent with provisions of the Conflict of Interest Statement on the reverse.

Exhibit III-7

CERTIFICATION REGARDING CONFIDENTIALITY OF INFORMATION

I fully understand the confidential nature of the application, proposal, or active project evaluation and review group discussions related thereto and agree:

1. to destroy or return all review-related materials;
2. not to discuss these materials or the review proceedings with any individual except those directly involved in the review;
3. to refer all inquiries made of me concerning any aspect of the review proceedings to the Designated Federal Official in charge of the review.

Printed or Typed Name Signature Date Signed

Exhibit III-8

Conflict of Interest and Confidentiality of Information

This will certify that in the review identified below, I did not participate in the evaluation of any grant or fellowship application from:

1. Any organization, institution, or university system in which a financial interest exists to myself, my spouse, parent, child, or collaborating investigators.

2. Any organizations in which I serve as officer, director, trustee, employee, or collaborating investigator.

3. Any organization with which I am negotiating or have any arrangements concerning prospective or other such associations.

Moreover, I fully understand the confidential nature of the applications and committee discussions related thereto and agree: (1) to destroy or return all review-related materials, (2) not to discuss these materials and the review proceedings with any individual except the Designated Federal Official, and (3) to refer all inquiries made of me concerning any aspect of the review proceedings to the Designated Federal Official.

(Printed Name)	(Signature)
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____
_____	_____

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel:

_____

_____

Meeting Date(s):_____

Exhibit III-9

Sample "Determination to Close" Memo:

(Date)

Director,

CIO Request for Determination to Close Portions of the Meeting for Announcement **(INSERT NUMBER)** Application Review

Associate Director for Management and Operations, CDC

ISSUE

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Cooperative Agreements for **(INSERT NAME of ANNOUNCEMENT)** Program Announcement **(INSERT NUMBER)**, will hold a meeting on **(INSERT DATE)**, to review applications. The meeting will concern subject matter considered confidential under the terms of Section 552b(c)(4) and (6), Title 5, U.S.C., and Section 10(d) of Public Law 92-463. Accordingly, I request that portions of this meeting be closed to the public.

DISCUSSION

The meeting will include the review, discussion, and evaluation of applications received in response to **(INSERT NAME OF ANNOUNCEMENT)** project cooperative agreements. The applications being reviewed include information of a confidential nature, including personal information concerning individuals associated with the applications.

RECOMMENDATION

It is recommended that the attached Determination to close the application review portion of the **(INSERT DATE)**, SEP meeting be signed.

Signature, Director, CIO

Attachments:
Determination
Agenda

Exhibit III-10

Determination

A portion of the **(INSERT DATE)**, meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: Cooperative Agreements for **(INSERT NAME of ANNOUNCEMENT)** Program Announcement **(INSERT NUMBER)**, involves the review, discussion, and evaluation of applications received in response to **(INSERT NAME OF ANNOUNCEMENT)** cooperative agreements. The applications being reviewed include information of a confidential nature, including personal information concerning individuals associated with the applications. For these reasons, this meeting is exempt under 5 U.S.C. 552b(c)(4) and (6) from mandatory disclosure.

Therefore, pursuant to the delegation of authority from the Assistant Secretary for Health effective **(INSERT DATE)**, to the Director, Centers for Disease Control and Prevention (CDC), re-delegated to the Associate Director for Management and Operations effective February 16, 1995, it is hereby determined in accordance with the provisions of Section 10(d) of Public Law 92-463 (5 U.S.C. App.2) that a portion of the meeting referred to above will be closed as indicated.

_____ _____

Date Associate Director for Management and Operations, CDC

Disease, Disability, and Injury Prevention and Control
Special Emphasis Panel Meeting: Cooperative Agreements for **(INSERT NAME)**
Program Announcement **(INSERT NUMBER)**

Name of CIO
Centers for Disease Control and Prevention
Address
Atlanta, Georgia

AGENDA

(Open to the Public)

8:30	Welcome/Introduction
8:40	Panel Instructions
9:00	Conflict of Interest Instructions

(Closed to the Public)

9:15 - 4:30	Review of Applications

Exhibit III-11

Sample of Meeting Minutes

Centers for Disease Control and Prevention
Minutes of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: **(NAME OF PANEL)**

(Date)
The meeting of the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel: **(NAME OF PANEL)** was convened on **(DATE)** at **(time)**, at the **(FULL ADDRESS)**. **(INSERT NAME OF CHAIRPERSON)** presided as Chair. The attached roster includes all members of the panel. Others in attendance included: **(LIST)**.

This meeting was closed to the public in accordance with provisions set forth in section 552b(c)(4) and (6), Title 5 U.S.C., and the Determination of the Associate Director for Management and Operations, CDC, pursuant to Pub. L. 92-463. The Designated Federal Official explained policies and procedures regarding avoidance of conflict of interest situations, voting and priority ratings, and confidentiality of application materials, committee discussions, and recommendations.

The Committee reviewed ____ applications requesting $_____ in support. _____ applications were recommended for $_____ in support and _____ applications were judged to be noncompetitive (NC).

ADJOURNMENT
The meeting was adjourned at _____ on _____.

CERTIFICATION
I hereby certify that the foregoing minutes are accurate and complete.

_____ _____
Date Chairperson (Name)

_____ _____
Date Designated Federal Official (Name)
Attachment:
Roster

Exhibit III-12

ROSTER

The SEP Member Roster should be similar to the following example:
SEP Member Roster
Panel Name _____ Meeting Date _____

Note each entry for each panel member should include:

Member Name
Organization
Title
Address
Phone Number

CHAPTER IV
First Level of Review: Participants and Pre-Meeting Activities

CHAPTER CONTENT

KEY PARTICIPANTS IN THE PEER REVIEW PROCESS

EXECUTIVE SECRETARY

The Executive Secretary (ES) is the CDC/DFO responsible for the management of a SEP or chartered committee. The ES plays a key role in a number of crucially important aspects of the peer review process. These include:

- Identifying and recruiting highly-qualified scientists to serve on peer review panels.
- Selection of a senior member of the scientific community to chair each review panel.
- Maintaining liaison with panel members about technical and administrative issues.
- Conducting an administrative review of each application assigned to a panel for review.

- Matching panel expertise with application content in deciding on panel member review assignments.
- Preparing a panel meeting agenda.
- Working closely with the Review Technical Assistant (RTA) to ensure the adequacy, appropriateness, and efficiency of logistical requirements for the panel meeting.
- Managing the formal panel meeting working in close tandem with the chair.
- Preparing a summary statement reporting the reasons for panel recommendations and ratings for each application reviewed.

Ideally an Executive Secretary should have:

- Past experience with the peer review process.
- Knowledge in the relevant biomedical or behavioral scientific area.
- A good working knowledge of the scientific community, including where and how to obtain helpful information for the recruitment of expert peer reviewers, e.g., professional societies, professional journals, key personnel in federal agencies, directories and databases, sponsors of research programs at minority institutions, personal files based on past experience, etc.
- Good interpersonal skills, including the ability to cooperate and interrelate well with colleagues and peer review participants is essential.
- Good communication skills—both written and oral.
- Leadership abilities to properly manage a panel of peer reviewers. It is essential that each Executive Secretary be capable of articulating pertinent review policies and procedures and see to it that they are adhered to in the review of applications.
- Effective listening and note taking skills during meeting discussions.
- Good judgement, objectivity, and fairness.
- The ability to complete task assignments in a timely and highly professional manner.

SCIENTIFIC PANEL MEMBERS

The primary requirement for serving on SEP or a study section is demonstrated competence and achievement as an independent investigator in a scientific or clinical discipline or research specialty. Assessment of such competence is based on the quality of research accomplished, publications in refereed scientific journals, and other significant scientific activities, achievements, and honors. Usually, a doctoral degree or its equivalent is required. Service also requires mature judgement, balanced perspective, objectivity, ability to work effectively in a group context, commitment to work assignments, personal integrity to assure the confidentiality of applications and discussions, and the avoidance of real or potential conflicts of interest.

In addition, factors such as geographic distribution and adequate representation of ethnic minority and female scientists must be considered. Further, no more than one member from the same organization may be appointed at the same time. An interval of one year is to occur before a retiring reviewer can be reappointed to the same or another CDC committee, and no one may be appointed to serve simultaneously on two CDC committees. (Exceptions to these restrictions may be requested and must be approved by CDC officials).

CDC solicits a wide variety of professional societies and organizations to identify as many potential reviewers and members as possible.

Appointments to SEP's are for a particular meeting and have been delegated to the Director, CDC. Appointments to a chartered study section or advisory committee are made by the Secretary of HHS for up to 4 years and staggered so that about a fourth of the membership of a group is new each year.

In summary, the primary criteria for selection of scientific panel members are:

- Requisite scientific expertise and research experience.
- Prior peer review experience desirable but not essential.
- Respect among peers.
- Quality of research/programs accomplished.
- Publications in refereed scientific journals.
- Other significant scientific activities, achievements, and honors.
- Objectivity, fairness and good judgement.
- Ability to work well in a group situation.
- Good communication skills, written and oral.
- Commitment to complete panel assignments and responsibilities.
- Assurance to protect the confidentiality of applications.
- Avoidance of real or perceived conflicts of interest.

Additionally, the following general guidelines are followed in the selection process. The intention is to assemble peer review panels with the right blend of maturity, diversity, expertise, and viewpoints and to provide realistic workloads for individual panel members.

- It is recognized that members of the scientific community are very busy individuals with teaching duties, research responsibilities, administrative duties, preparing manuscripts and books for publication, peer reviewing articles for journals, preparing grant applications, etc. Therefore, typical reviewer workloads should be approximately 6 applications per meeting. This is not an absolute requirement since in the judgement of the Executive Secretary a few more or a few less may be indicated. However, the message is to not overburden reviewers.

- One-third of the membership of each panel should consist of new members. It is recognized that review continuity is important but it is equally important to infuse the process with new perspectives and viewpoints and not rely on re-invitations over and over again to members who have served previously.

- There should be a good blend of reviewers at the senior (Professor), intermediate (Associate Professor) and junior (Assistant Professor) levels. Because it is important to recruit younger, well-qualified scientists, encouragement is given to recruiting approximately 20% of the panel at the Assistant Professor or equivalent level.

- Panel membership diversity is important. Significant representation of women and minority scientists is not only desirable but strongly encouraged.

No more than one panel member should be recruited from any one institution. If for some reason a waiver of this provision is required, approval must be obtained. Each campus in a multi-campus university system is considered a separate institution (see Chapter VIII, page 4 for details).

- CDC employee participation as reviewers should be discouraged due to perceived or real conflicts of interest. Reviewers from other agencies are allowable with no restrictions as to agency, e.g., VA, NIH, FDA, etc., up to one or two per panel.

- Scientists from foreign countries are not eligible for participation except in special situations for which approval from the CMO is required.

Also, Executive Secretaries are encouraged to add panel members with unique perspectives. For example, in the area of drug development, evaluation, and related topics, experts from the pharmaceutical industry have valuable practical as well as scientific experience to contribute to panel discussions and recommendations. The same principle can be applied to almost every scientific subject area under panel review in terms of experts in relevant research in the private sector.

PANEL CHAIRPERSON

The choice of a panel chair should be completed early in the process. Aside from the selection criteria for scientific reviewers, other factors that may be considered in the selection of the chair include:

- Is the individual a senior scientist, highly respected in the areas of science relevant to the panel review responsibilities?
- Does the individual possess experience in service with other peer review panels?
- Does the individual possess experience leading a research program?
- Does the individual have a history of peer review support?
- Does the individual possess the ability to chair a meeting by exhibiting strong leadership and fair but firm moderation of scientific discussion and debate?
- Does the individual possess the ability to summarize the substantive highlights of panel application discussions?

- Does the individual exhibit a willingness to work cooperatively with the panel Executive Secretary and RTA?
- Does the individual exhibit a willingness to adhere to and ensure that the review policies and procedures will be followed by the panel.

Once panel chairs are selected they can be a good source of names of potential reviewers. *It is important to remember to keep the chair informed of any relevant information affecting plans for the panel meeting. Executive Secretaries should obtain a CV from each recruited panel member for their own information and for the RTA so that panel rosters and other review-related materials can be generated.*

REVIEW TECHNICAL ASSISTANT

The Review Technical Assistant (RTA) provides comprehensive administrative and logistical support for the review process. This support includes pre-meeting and onsite meeting support for Executive Secretaries; preparation and setup of the meeting room; reproduction of any materials needed by the review panel for pre-meeting, meeting, and post-meeting activities; distribution and collection of meeting materials to all participants; and ensuring that reviewers accurately record their votes. The RTA receives technical guidance and task assignments from the Executive Secretary.

RECRUITMENT OF REVIEWERS

There are several considerations to be mindful of when recruiting reviewers. They should be recruited as early as possible; this activity is a critical part of the time line formulated for each RFA. "The sooner the better," should be the recruitment motto. Reviewers are busy and key activities or events in their routines are scheduled months in advance. Members of chartered committees have an advantage in that they usually meet on a regular basis each year and can mark their calendars accordingly. Recruiting members for SEPs is different since this type of panel meets on a one-time-only basis according to need. Recruitment in this case can start on a tentative basis much before an RFA is approved and released. If reviewers express a desire to serve, they can be asked to block off time on their schedules and hold it until it is certain that the RFA will be released. At the very least a core group of reviewers should be contacted early for this purpose.

The number of panel members recruited is determined by panel workload. The formula used is based on the number of applications on the panel agenda, multiplied by a minimum of three reviewers required for each application, divided by 6 representing an average workload per member, and anticipating that approximately ten percent of reviewers will drop out prior to the meeting.

In the case of panel chairs, it is recognized that they have additional responsibilities in moderating the scientific portion of the panel meeting. Therefore, a lighter application workload may be in order but the number is left to the discretion of the Executive

Secretary with the expectation that the chair will be asked to review some lesser number of applications. In this example:

- Number of anticipated applications is 25
- Number of reviews per application is three
- Number of applications to be reviewed per reviewer is six
- Drop-out factor is ten percent (0.10)

The number of reviewers required is (25 x 3)/6 x 1.1 = 13.5 or 14 per panel

The number of applications received for an RFA initiative will dictate the number of panels required. A workload of 25 applications per panel can be comfortably reviewed in one day especially if a streamline review procedure is used. For example, a panel meetings can be set to begin with an evening session at approximately 7 P.M. If more than one panel is involved, the meeting can begin with a plenary session to include a programmatic discussion of the RFA, review procedures and housekeeping matters. This session can be followed by the convening of individual panel meetings and proceeding with a streamline review process that should reduce 25% to 50% of the applications from further in-depth review. The next morning each panel should have little difficulty completing its business of a full discussion of each remaining application by early afternoon. However, this is only one method of arranging a meeting schedule. There are undoubtedly others that can be used at the discretion of the CIO staff.

OTHER IMPORTANT PRE-MEETING RESPONSIBILITIES

HOTEL ARRANGEMENTS

As soon as possible, decide on a hotel site for the meeting. Committee meetings are usually held at a CDC facility. However, because so many panel rooms are needed for this type of meeting, a hotel has turned out to best accommodate meeting needs. Nine to twelve months prior to the meeting is not too soon to make a selection and to work with the hotel on tentative arrangements. Check with the hotels around town. Several site visits to hotels may be necessary before making a final decision. Many attendees like to be close to the airport. If not close to the airport, then a location should be selected where there are a variety of places to eat and things to do.

STEPS

1. After a hotel site has been selected, write a letter to the Sales Manager reiterating details of the arrangement. The hotel should acknowledge in writing with a tentative agreement. Thank you letters may also be written to those hotels not selected in appreciation for their time and hospitality.

2. Within the last 3-month period, make arrangements with vendors and initiate requisitions for meeting room rental with the hotel, a copier, speaker phone, and any audio visual equipment required.

3. Upon receipt of the applications (about four to six weeks before the review meeting), the Executive Secretary should be able to make a determination of how many reviewers will be needed. Based on this determination, notify the hotel of the number of guest and meeting rooms required. Process final purchase order with the hotel and other vendors.

4. After inviting and receiving commitments from reviewers who will attend, provide the hotel with a participant list which can assist in tracking those individuals who have not confirmed reservations with their credit card.

5. Within the last month, keep tabs on reviewers who have not confirmed their room, and prompt them to do so by the hotel deadline. Also, double check that all audio-visual equipment needs have been established and provided.

PREPARE MEETING AGENDA, FEDERAL REGISTER NOTICE, DETERMINATION TO CLOSE A PORTION OF THE MEETING

NOTE

These documents take several months to prepare and process. Don't wait until the last minute! Examples of these exibits are provided at the end of Chapter III.

AGENDA

Using a former agenda to prepare a draft, the Executive Secretary can prepare an agenda on an as needed basis. The Executive Secretary should confer with the chairperson of the committee before the agenda is cleared. The final agenda should be cleared internally within the CIO.

Copies of the final agenda are included in the reviewer packets; a second copy is provided in the on-site packets.

Public Notice of a Federal Advisory Committee Meeting

Each federal advisory committee meeting, whether it is open or closed, must be announced in the Federal Register at least 15 calendar days prior to the meeting. Whenever possible, 30 days notice should be given.

Request for Determination to Close Committee Meeting Memo

As soon as the agenda for the meeting is finalized, a Request for Determination to Close Committee Meeting memo needs to be produced. As soon as the determination has been signed by the Director, CDC, the FRN should be processed through the CDC/CMO Office.

Closing Federal Advisory Committee Meetings

The Executive Secretary makes a written request to fully or partially close a meeting to the public to the Director, CDC, for approval. This request must be cleared by the Office of General Counsel, CDC, and be sent to the HHS Freedom of Information Officer, Office of Public Affairs, Office of the Secretary, who is the designated approving official. The request should be submitted at least 60 days before the scheduled meeting date.

The signed Determination remains in the committee's official file and is made available for review on request.

A copy of the Determination must be sent to the Department Committee Management Officer at the same time that it is forwarded to the HHS Freedom of Information Officer.

More detailed information concerning this and other meeting requirements can be found in Part IV - Meetings of Federal Advisory Committees in the Federal Advisory Committee Management Handbook.

APPLICATION RECEIPT

Grant applications submitted to the CDC are received by the Procurement and Grants Office (PGO), numbered, and copies sent to the appropriate CIO. The PGO assigns each application are given a six digit control number and a suffix that shows the application's submission status [e.g., a first submission may read 123456-01, whereas a resubmission (amended application) may read 123456-01A1]. Two resubmissions are permitted after the initial submission. If this suffix is kept as a separate field in the database described below, it can be used as a field upon which to sort. This will be helpful in determining resubmissions and pulling previous summary statements for the reviewers to determine whether previous weaknesses and comments have been addressed.

Explanation of Suffixes	
01	**Represents the year of funding**
A1	**Signifies the first resubmission with modifications**
S1	**Signifies a supplement to the application**

Applications are distributed as follows:

PGO keeps the original application.
1 copy to the primary reviewer.
1 copy to the secondary reviewer.
1 copy for a reader.
1 file copy.

1 library copy.
1 chairman's copy.
1 copy for a supplemental reviewer (optional).

DATABASE INPUT

The database fields contain information important to each application such as the application number, principal investigator, institution, assigned reviewers, year of review, cycle, and direct cost (see printout of file configuration). All of this information, with the exception of the assigned reviewers, can be found in the application. However, this is a time consuming process and will take about a week to complete.

EXPLANATION OF DATABASE FIELDS

1. Year—Refers to the Fiscal Year of the receipt of application.
2. Cycle—If there is more than one submission date per fiscal year, it is helpful to break them down by cycle (ex. A, B, C, etc...). This way, one is able to refer to all applications for a particular submission date by the year and cycle (ex. 91-A refers to all of our applications submitted on October 1, 1990). 91 is the fiscal year/A is the first submission date within the fiscal year.
3. Grant Number—Refers to the six digit number assigned to the application by PGO.
4-6. Grant Suffixes show the submission status.
7. Project Title—A title given the project/application by the principal investigator.
8. FNAME–The first name of the principal investigator.
9. LNAME–The last name of the principal investigator.
10. Degree—The advanced degree, if any, of the principal investigator.
11. Institute—The institute which is submitting the application.
12. Year 1 DC—Year one direct cost.
13. Year 1 TC—Year one total cost.
14. DC2—Direct cost for year 2.
15. DC3—Direct cost for year 3.
16. DC4—Direct cost for year 4.
17. DC5—Direct cost for year 5.
18. Proj DC–Direct cost for the entire project.
19. Proj TC–Total cost for the entire project.
20. FN Rev1–First name of primary reviewer.
21. LN Rev1—Last name of primary reviewer.
22. FN Rev2–First name of secondary reviewer.
23. LN Rev2—Last name of secondary reviewer.
24. FN Rev3–First name of supplemental reviewer.
25. LN Rev3—Last name of supplemental reviewer.
26. Research category—Category into which the application is placed.
27. Panel—Panel to which the application is assigned (Ex. A, B, C, etc...).
28. State—State from which the institution/principal investigator are applying.

29. Recommendation—This information will need to be added after the technical/primary review. It is simply the record of applications that were scored, unscored, or disapproved. It has no relation to the actual funding of any of the approved applications.

INITIAL APPLICATION SCREEN FOR RESPONSIVENESS

All applications should be subjected to an administrative staff review, usually conducted by the Executive Secretary, to ensure responsiveness to the program announcement or RFA. The review is based on completeness of the application so that it can be satisfactorily peer reviewed, eligibility, consistency with the published program requirements, and relevance to the objectives of the announcement. It is appropriate for the Executive Secretary to request an independent responsiveness review of each application from another CIO staff member. Disagreements should be discussed but the bias should be for inclusion of the application. Additionally, applications should not be excluded on the basis of staff judgements of scientific merit. A sample worksheet for determining responsiveness or lack thereof is presented below as well as a sample memo explaining to the PGO why applications must be returned to the applicant. A sample worksheet is shown as Exhibit IV-1, page IV-20.

ASSIGNMENT OF APPLICATIONS TO REVIEWERS

This is a responsibility of DFO, which is not to be delegated and includes:

- Assignment lists are confidential.
- Reviewers must have no real or perceived conflict of interest.
- Need to match expertise of reviewer with research content of application.
- Must ensure that each application will receive an adequate review .

The purpose of the peer review process is to ensure a fair and thorough scientific review of all submitted grant applications. The assignment of reviewers to applications is a critical step in this review process. Assignment of applications to a review panel and to particular reviewers must take into account two factors - the specific technical/scientific expertise of the individuals selected to serve as peer reviewers and the need to avoid real or perceived conflicts of interest.

The following is a sequential listing of activities to be performed in assigning reviewers to a research grant application.

Develop a list of universities and affiliations of members of the federally chartered external merit review group (Study Section) and potential members of the SEP and other *ad hoc* reviewers.

The applications should be broadly divided into major groups, e.g., research that deals with epidemiology and health services and sciences that deal with various clinical or behavioral

disciplines. Depending on the number of applications in each of these groupings, either one or several panels may be established. The number of reviewers needed is approximately half or less than that of the number of applications received. To achieve the best discussions, the panel size should range from no less than nine members to a maximum of 15. An individual reviewer generally should have no less than three and no more than six assigned reviews, primary, secondary or reader assignments. Thus, if 100 applications were received, one could expect to invite 55 reviewers, subdivided into four or five panels.

For the aforementioned groupings, create a list of affiliations of the principal investigators and listed research team members including consultants. This can be obtained from the database.

If the number of submissions requires more than one panel in a particular area, reviewers are assigned to one or another panel. This should take into account the organizational affiliation of each reviewer with panel assignments being made so as to limit the number of recusals, and to provide the scientific expertise needed on each panel.

At this point, there can be a preliminary matching of applications to reviewers with like expertise. Recruitment of additional ad hoc reviewers for panels will be made when necessary with consideration again of organizational affiliation and additional requirements of scientific and technical expertise for specific reviews. In some cases when there is a application that requires specific expertise that is not represented on the panels, the executive secretary may request that an outside supplemental mail review be obtained. This step is taken after conferring with the chairperson of the panel. Ideally, arrangements should be made to have the supplemental reviewer participate in the panel discussion by telephone.

REVIEWERS' RESPONSIBILITIES

There are usually three types of reviewers: primary reviewer, secondary reviewer, and reader.

A PRIMARY REVIEWER - Prepares a complete written review using the specially designed form provided. The review should provide sufficient detail regarding the entire project; the reviewer serves as the primary discussant during the panel deliberation of the application.

A SECONDARY REVIEWER - Prepares a complete written review using the form as provided except that page 1 (description of the project) is omitted. The written review should provide particular emphasis on the reviewer's special area of expertise - either the major objective of the RFA (prevention, evaluation, etc.) or discipline (e.g., epidemiology, chronic diseases, infectious diseases, occupational diseases, injury, the environment, criminology, health policy, or economics). The reviewer serves as a secondary discussant during the panel deliberation of the application.

A READER - Reads the entire application. The reader's written review consists only of detailing the overall strengths and weaknesses of the application with particular emphasis on

the reviewer's special area of expertise. The reader serves to provide additional insight during the panel deliberation of the application.

Reviewers will receive the following materials prior to the review:

- Copies of their assigned applications.
- Abstracts of all applications to be reviewed by the panel.
- Instructions for the way written comments are to be prepared.
- Pertinent meeting information.

In addition to assigned applications for written comments, each reviewer is asked to read and become familiar with the abstracts of all applications to be considered.

INSTRUCTIONS FOR REVIEWERS' WRITTEN COMMENTS

Each member is expected to read and become familiar with assigned applications and abstracts. The Executive Secretary assigns each application to one primary and one or more secondary reviewers for detailed written reviews. Additionally, readers or discussants are assigned and expected to prepare less formal comments highlighting strengths and weaknesses. If additional information from the applicant is needed, reviewers should inform the Executive Secretary well in advance of the meeting. Reviewers **must** not contact an applicant directly. All communications with applicants must be handled by the CIO staff, in this case the Executive Secretary.

Preliminary reviewer comments should be returned to the review office as early as possible, so that the Executive Secretary can read all reviews and be aware of any major difficulties or differences of opinion. Moreover, if questions have been raised, the Executive Secretary can often obtain answers before the meeting. The reviewers' written comments and the subsequent discussions during the review are the basis for the final recommendation of the panel and for the summary statement prepared by the Executive Secretary that, in turn, is transmitted to the second level of programmatic review and eventually to the applicant principal investigator. Consequently, the reviewers' comments should be suitable for their intended uses in format, content, and phrasing. Reviewers must provide specific written substantiation of their recommendations. Unexplained abbreviations and laboratory jargon should be avoided.

Generic Content of Form for Reviewer's Comments

The general principle to follow in preparing a suitable form is that it should be organized around the published review criteria for the specific solicitation. The preliminary written comments by the reviewers serve as the content material for the preparation of the summary statements documenting the panel recommendations for each application. Detailed instructions to reviewers should be provided by the Executive Secretary. More information about the preparation and importance of summary statements is included in Chapter VII. General information is provided below.

Description

Use the application abstract unless inappropriate, making sure the objectives and procedures are clearly and concisely described. Do not include evaluative statements in the description.

Critique

Do not include descriptive information in this section. Address the strengths and weaknesses of each of the **review criteria specified in the RFA**. (Reviewers should know that applicants are instructed to limit their Research Plan to no more than 25 pages.) Descriptive phrases meant to be critical should be avoided; constructive evaluative comments are required . If applicable, for deferred or revised applications, evaluate changes since the previous review. If applicable, for competing continuation (renewal) and supplemental applications, evaluate the past performance.

Investigators

Assess the competence of the principal investigator and key personnel to conduct the proposed research. Comments about past performance, training, and/or track record are appropriate and helpful.

Resources and Environment

Evaluate any special attributes or deficiencies relevant to the conduct of the proposed studies.

Budget

Evaluate the direct costs only. Determine whether all items of the budget in all requested years of support are appropriate and justified. Provide a rationale for each suggested modification in amount or duration of support. For supplemental applications, comment on the requested budget in relation to the parent grant.

Other Considerations

Comment on the adequacy of the protection of human subjects and their data. In the case of studies involving human subjects, comment on the inclusion of women and minorities. If applicable, comment on the adequacy of the protection of animals and the presence of any biohazardous procedures harmful to project investigators or study subjects.

Overlap

Identify any apparent scientific or budgetary overlap with active, pending, or planned support. Include in your consideration of overlap any non-CDC support. Potential overlap does not affect the merit review of an application, but will be identified on the summary statement for subsequent staff action.

Foreign

Comment on any special talents, resources, populations, or environmental conditions that are not available in the United States or that augment existing United States resources. Indicate whether similar research is being done domestically and whether there is a need for such additional research. Uniqueness is not a necessary criterion.

SPECIAL CONSIDERATIONS:

RESUBMITTED APPLICATIONS: With regard to resubmitted applications, the Executive Secretary should make a reasonable effort to attain consistency in the current review from the previous review(s). At least one of the reviewers (primary, secondary, reader or supplemental) should be a reviewer from the previous submission if possible. A reminder below should be sent to reviewers.

NOTE TO REVIEWERS OF RESUBMITTED RESEARCH GRANT APPLICATIONS

This grant application was reviewed at a previous meeting. The summary statement describing that meeting's panel deliberations is provided for your additional information. Please use the information contained in the summary statement to assess the applicant's response to recommendations from the previous review.

Please add these questions to your "Form for Preparation of Written Comments":

What modifications were made in this project as a result of the summary statement?
Were all concerns in the summary statement properly addressed?

SUPPLEMENTAL REVIEWS: Supplemental reviews will be read at the panel meeting by either the chair or co-chair. Supplemental reviews should be assigned and sent (with evaluation forms) to the reviewer so as to allow adequate time for the written evaluation to be received by CDC and sent to the panel chair and co-chair before the meeting.

AD HOC PANELISTS AND SUPPLEMENTAL REVIEWERS

The RTA should keep in touch with reviewers by phone or fax or e-mail to confirm dates. Then, soon after the receipt of applications and before mail-outs, contact all of the reviewers to confirm that they will attend the meeting. Some of them may not be able to attend and replacements may be needed. Legally, in order to hold the review, a quorum is needed which means that more than fifty percent of the reviewers must attend. In some cases, due to a larger than expected number of applications, more reviewers may be needed than originally anticipated. When this happens, ad-hoc panelists and supplemental reviewers are recruited. Ad-hoc reviewers attend the meeting, review applications, and participate in all the procedural functions in the same way as other SEP members. In the case of chartered committees, the only difference between an ad hoc reviewer and a committee members is that they cannot vote on subcommittee reports at closing plenary sessions. Supplemental reviewers submit a written evaluation by mail but do not attend the meeting.

Ad Hoc Reviewers

Recruiting Ad Hoc panelists can be difficult and time consuming. A list with many alternates should be developed in case it is difficult to reach a particular individual. Many calls may be made in an attempt to reach one individual who may then be unavailable because of a scheduling conflict. Depending on how many ad-hoc are required, a minimum of one week should be set aside to complete this step in the process.

Supplemental Reviewers

Recruiting supplemental reviewers is not quite as difficult. They are generally cooperative since they are not required to travel to the meeting. Be very specific about what is expected of them when making the initial contact. Also, it is helpful to have a firm due date for the application evaluation and its return (along with the application) several weeks preceding the review. This will allow for a buffer of a few weeks should the review not be sent in time. Also, the primary and secondary reviewer may wish to read this individual's review before the meeting.

Steps involved with supplemental reviewers:

Recruit reviewers by phone.
Mail applications to supplemental reviewers.
Follow up calls to supplemental reviewers who have not submitted their written reviews in a timely way.
Send thank you/reimbursement letter to supplemental reviewer.
Reimbursement is for one day regardless of the number of assigned reviews.

REVIEWER ASSIGNMENT LISTS

Two different tables containing much of the same information in varying formats are needed to organize the mailing of review packages to reviewers (see examples provided). This information can be taken from the database file.

By Reviewer

Reviewer	Primary Review (App. #)	Secondary Review (App. #)	Panel
alphabetically			

Table 1.

By Application			
Application #	Primary Reviewer	Secondary Reviewer	Panel
numerically			

Table 2.

MEETING LOGISTICS

To all reviewers:

Send a letter to panel participants with all of the meeting details well in advance of the meeting. A sample letter, shown as Exhibit IV-2, page, IV-21, can be modified as desired by the individual CIO.

CONTENT OF REVIEWERS' PACKETS

Match up applications with reviewers according to the assignment list(s).

Create Reviewer's information packet.

LIST OF CONTENTS:

In notebook form:
Letter to reviewers
Table of Contents
Agenda
List of participants by panel
Request for Applications (RFA) or Program Announcement (PA)
Evaluation form for preparation of reviewer comments
List of applications by principal investigator
Personalized assignment sheet
Streamlined (Triage) Recommendation Form
Numerical listing of applications by panel
Background information on the program's priorities
Meeting logistics information

Also included in the packet:
All applications to be reviewed by reviewer plus abstracts of other applications
Summary statements of resubmitted applications
Orientation Material for members of a SEP (see Appendix II)

Revise Reviewer's packet as needed and finalize.

Frequently, reviewers will drop out or something else will happen causing revisions in the packets to be made. If possible, these modifications should be made before the packet is finalized.

Reviewer packages should be sent by overnight mail. This is done to ensure speedy delivery and to ensure maximum time for reviewers to review the applications. Also, if the packages are lost, they can be easily traced.

Confirm receipt of applications

This turns out to be an important step as someone may claim they didn't receive an item. One of two things will have happened. They will have received the item and then misplaced and forgotten it. Likewise, you may have neglected to send something important and this then provides you ample time to get the information to the reviewer. Either way their receipt of applications will be documented.

PREPARE ON-SITE MEETING PACKET MATERIALS

Meeting packets

Each individual's packet should be labeled with the reviewer's name. You can take this opportunity to insert papers, memos, etc., which are specific to that person. Also, there are items specific to chairs and vice-chairs that should be included at this time also.

Items to be included are:
1. Reviewer's application list
2. Reviewer's recommendations form
3. Summary of review and voting procedures
4. List of participants (self-explanatory).
5. Reimbursement form
6. Instructions on how to fill out the reimbursement form
7. Pre-paid, pre-addressed envelope

Item specific to chairs and vice-chairs:
1. Chair's Guide for Review Conduct
2. Supplemental reviews, if any

STAFF MEETING PACKETS

The staff members have made a list of items they have found helpful. These should be combined into a Staff Notebook. The items are:

1. Abstracts of all applications (include all summary statements from previous submissions)
2. A copy of the reviewers' packets
3. Recommendation sheets
4. Order of application review*
5. List of participants
6. List of applications by principal investigator

* Review order should be randomly assigned.

PANEL EXECUTIVE SECRETARY PACKETS

These should be prepared a week or two prior to the review to enable the Panel Executive Secretaries to become familiar with the applications on their panel. This packet includes, but is not limited to, the following items:

1. Guide for Executive Secretaries for Grant Review Panels (see next chapter)
2. Points to Remember for Executive Secretaries
3. Conflict of Interest passages to be read
4. Attendance Roster
5. Abstracts and previous summary statements of all applications to be reviewed by that panel.

Chairs and Vice-Chairs

Chairs and vice-chairs should receive abstracts of those applications to be reviewed by their panel several weeks prior to the review.

COPIES OF SUPPLEMENTAL REVIEWS FOR CHAIRS AND CO-CHAIRS

Generally, the chair or vice-chair will read the supplemental review aloud to the panel. A copy should be mailed two or three weeks ahead of time so the chair/co-chair will have time to become familiar with the review. This can be mailed at the same time the abstracts are sent.

ADDITIONAL APPLICATION MATERIAL

Call the PGO Grants Specialist two weeks before the review about any information received after submission date. Make copies and distribute to reviewers as necessary.

Although not a good practice, this may have to be done at the very last minute and inserted into the reviewers' on-site packet. If this is the case, the reviewers should be informed during the opening meeting to enable them time to review the information if necessary before the panel discussions begin. This is only practical if the amount of material to be inserted is minimal. Otherwise a separate mailing prior to the review may be required to enable the reviewers time to review the material.

Exhibit IV-1
Sample Worksheet for Responsiveness

Date:

From: Executive Secretary

Subject: Unresponsive Grants to Program Announcement **(INSERT NAME)**

To: First Name, Last Name, PGO

Through First Name, Last Name, Director [of CIO] _____

We recommend that the following three (3) applications not be peer-reviewed because they are unresponsive to program announcement **(INSERT NUMBER)**, including not meeting specific program requirements (PR):

Grant #: XX-XXXX Grant Title: P.I.:
Reasons for unresponsiveness: (PR#B) The applicant's project team lacks demonstrated experience in conducting, evaluating, and publishing [area-related] research as defined in the program announcement. (PR#C, D) There are no letters of support and commitment from outside entities, such as advisory panel members and three proposed sites for prevention, that would ensure implementation of the proposed activities. (PR#E) There is lack of a match between the applicant's proposed theme and research objectives, and the program priorities as described under the heading, "Programmatic Priorities, addressing [area-related].

Grant #: XX-XXXX Grant Title: P.I.:

Reason for unresponsiveness: (PR#A) The principal investigator did not provide documentation that he has published [area-related] research in peer-reviewed journals. (PR#B) The applicant's project team lacks demonstrated experience in conducting, evaluating, and publishing [area-related] research as defined in the program announcement. (PR#C,D) It is unclear if the applicants can carry out their research projects as described since the School District has given only tentative support (contingent on further review) and no support or commitment has been received from individual schools in which research would take place.

Grant #: XX-XXXX Grant Title: P.I.:
Reason for unresponsiveness: (PR#B) The applicant's project team lacks demonstrated experience (only one published article) in conducting, evaluating, and publishing [area-related] research as defined in the program announcement. (PR#C,D) There are no letters of support and commitment from outside entities—such as schools—that would ensure implementation of the proposed activities.

Exhibit IV-2
Sample Letter to Reviewers

Dear

Thank you for agreeing to assist with the review of grant of applications received in response to RFA:**(INSERT NAME)**. The meeting is scheduled to take place on **(INSERT DATE)**. To help you in making your travel arrangements, the details follow.

Meeting time and place: The meeting will begin **(INSERT DAY, DATE, and TIME)**. It will continue the next two days beginning at **(INSERT TIME, DAYS and DATES)**. It will be held at the **(INSET LOCATION).**

Airline reservations and compensation: Please note that **you are asked to make your own travel arrangements and purchase your airline ticket.** You will be reimbursed for regular round-trip coach airfare to Atlanta via the most direct route; additional costs resulting from indirect routing or stopovers will not be covered. You will be compensated by check six to eight weeks after the meeting.

Ground transportation in Atlanta: When you arrive in Atlanta, you may take a taxi from the airport. The hotel is located approximately 15 miles north of Hartsfield International Airport. Or, you may take the Atlanta Airport Shuttle ($8.00 each way) which runs between 7:10 a.m. - 7:30 p.m. every twenty minutes.

Hotel reservations: The **(INSERT HOTEL NAME)** has asked that you reserve your room as soon as possible, by calling **(INSERT PHONE NUMBER)**. Please identify yourself as a participant in the CDC-CIO meeting and provide a credit card number. The room rate will be **(INSERT $ AMOUNT)** plus tax.

Reimbursement: Please save originals of your hotel, airline, and parking receipts, as well as taxi receipts over $25.00, for reimbursement. In addition to reimbursement for your airline ticket, you will receive a per diem allotment of **($XXX.XX)** to cover meals and incidental expenses for each day of travel. Further, you will receive a consultant's fee of **($XXX.XX)** per day. More information on reimbursement will be provided to you at the meeting.

If you have any questions regarding travel arrangements, please call **(INSERT NAME**) at **(INSERT PHONE NUMBER)**. I look forward to seeing you in January.

Sincerely yours,

Executive Secretary

Exhibit IV-3
Sample Letter to Supplemental Reviewers

To supplemental reviewers:
Send a letter with details of what is required well in advance of the meeting.
Date

Dear

Thank you for agreeing to serve as a supplemental reviewer for the research grant application entitled **(INSERT TITLE)**. Your evaluation will be greatly appreciated by the other members of the peer review panel.

I am enclosing the grant application, and a suggested format for you to use in writing the supplemental review. Your written review will be shared with the panel. Please return your written review to my office by **(INSERT DATE)**. The address is:

Name of CIO
Centers for Disease Control and Prevention
Address
Atlanta, Georgia 30333

In addition to our heartfelt appreciation, you will receive a consultant's fee of **($XXX.XX)** per day; this compensation will be mailed to you within six weeks of the review meeting in June.

If you have any questions, please call me at **(INSERT PHONE NUMBER)**. Again, thanks for your participation.

Sincerely yours,

Executive Secretary

A good deal of material has to be prepared for each review meeting. Sample lists are described below.

CHAPTER V
First Level of Review: Meeting Activities

CHAPTER CONTENT

The day of the review meeting has arrived. What lies ahead? If more than one panel is required, it is advantageous to meet with all panel reviewers in a plenary session to discuss the RFA and any review procedures that are relatively new or different such as the streamlined (triage) review process. Other review procedures that are more standard should be discussed by the Executive Secretary at the beginning of each individual panel meeting. If only one panel is to meet then all program and review issues should be covered at the beginning of the meeting.

PLENARY SESSION

- At an early evening time designated by the staff, reviewers from each of the review panels are assembled for a plenary session to hear comments and answer questions from the staff about the RFA and related meeting matters. This is the open part of the meeting as advertised in the Federal Register. This is usually a short meeting with the following agenda:.

- Call to Order by Chair

- Introduction of key participants: These should include the Chairs of the panels, Executive Secretaries, Review Technical Assistants (RTA), Program Managers, and Grants Management Officers.

- Program Presentation: This is an important item reserved for the CIO program staff to brief the reviewers about the rationale, intent, and objectives of the RFA and to answer any questions the reviewers may have about its provisions and content. It is also an opportunity for officials of the CIO to brief the reviewers about any other matters of interest about the CIO such as plans for other RFAs or grant assistance programs, the status of the budget for extramural programs, and other programmatic issues of interest.

- Review Procedures: The Executive Secretary should describe several aspects of the review and how it is to proceed. For example, it might be well to indicate how many applications were received, on what basis the panels were configured, some estimate of the schedule, and any significant review procedure that might be best described at this session to ensure everyone receives the same message. The streamlined review process is a good example even though the concept has become well known and accepted by the scientific community. However, reviewers may not know how it is implemented by the CDC.

- Administrative Matters: A member of the staff should cover such matters as where the business office is located in the hotel, which member of the staff to contact for help with typing, printing, etc., who to contact to help with travel, location of the meeting rooms, and arrangements for coffee breaks and lunch. It is also important to remind reviewers to be sure to complete their expense vouchers and return them as soon as possible to ensure prompt payment.

- Comments by the Public: Before adjourning this public portion of the meeting, the Chair should requests comments from any member of the public who may be present.

INDIVIDUAL PANEL MEETINGS

After the plenary session, members will re-convene in closed meeting sessions in a meeting room assigned to their panel. A typical agenda follows.

Self-Introduction of Members and CDC Staff: The meeting should begin with self-introductions of panel members and observers. Members of the panel should be asked to identify themselves and their present affiliation and area(s) of expertise and interest. Staff members should be asked to similarly identify themselves and indicate areas of responsibility.

The Executive Secretary should introduce the RTA and describe duties assigned to this individual. For example, the RTA will be collecting essential documents, such as reviewer

comments and voting sheets, and notify the committee about missing information that is not accounted for. Reviewer requests for assistance from the RTAs should be coordinated with the Executive Secretary and Chair. The RTA will also maintain a record of those members who leave the room during the meeting because of a conflict of interest.

Administrative Presentation by the Executive Secretary: Issues that the Executive Secretary is required to raise during the administrative portion of the meeting are:

Conflict of Interest

At the beginning of each meeting, the Executive Secretary explains conflict of interest policy. Reviewers must leave the room when an application submitted by their own organization (see Chapters VIII for guidance related to multi-campus institutions) is being discussed. The same is true when reviewers, their immediate family, or close professional associate(s) have a financial or vested interest even if no significant involvement is apparent in the application. If the reviewer is available at the principal investigator's institution for discussions; is a provider of services, cell lines, reagents, or other materials; or a writer of a letter of reference, the reviewer must be absent from the room during the review. Reviewers are also urged to avoid any actions that might give the **appearance** that a conflict of interest exists, even though they believe there may not be an **actual** conflict of interest. Thus, for example, a reviewer should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Judgment must be applied on the basis of recency, frequency, and strength of the working relationship between the member and the principal investigator as reflected, for example, in publications. Another example might be a application from a scientist with whom the reviewer has had longstanding differences that can reasonably viewed as affecting the reviewer's objectivity. Another example is the review of a project which closely duplicates work ongoing in the reviewer's laboratory.

At the end of the scientific review group meeting, the Executive Secretary will obtain written certification from all reviewers that they have not participated in any reviews of applications when their presence would have constituted a real or apparent conflict of interest and that the confidentiality of actions will be maintained. In addition, each panel keeps a log, prepared by the RTAs of reviewers who left the room because of real or potential conflicts of interest.

Confidentiality and Communications with Investigators

All materials pertinent to the applications being reviewed are privileged communications prepared for use only by reviewers and staff, and should not be shown to or discussed with other individuals. Review group members must not independently solicit opinions or reviews on particular applications or parts thereof from experts outside the pertinent review group. Members may, however, suggest scientists from whom the Executive Secretary may subsequently obtain advice. Consultants are required to leave all review materials with the RTA at the conclusion of the review meeting. Privileged information in grant applications shall not be used to the benefit of the reviewer or shared with anyone.

Under no circumstances shall reviewers advise investigators, their organizations, or anyone else of recommendations or discussions of the review proceedings. The investigator may be led into unwise actions on the basis of premature or erroneous information. Such advice also represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of fellow reviewers serving on review committees. A breach of confidentiality could deter qualified reviewers from serving on review committees and inhibit those who do serve from engaging in free and full discussion of recommendations. Requests for additional information and telephone inquiries or correspondence from investigators must be directed to the Executive Secretary, who will handle all such communications.

Confidentiality of the panel proceedings is an especially sensitive matter because of the way many review sessions are structured. Many related panels may be meeting simultaneously; a particular panel may be reviewing applications submitted by members of other panels. Therefore, panel members should be reminded not to discuss panel business outside the meeting room.

Review Criteria

The reviewers will comment on the relevant review criteria in their written critiques in order to judge the likelihood that the proposed research will have a substantial impact on the pursuit of these goals. Each of these criteria will be addressed and considered by the reviewers in assigning the overall score weighting them as appropriate for each application. (The review criteria below are those used to evaluate investigator-initiated R01 research grant applications by the NIH and several CIOs at CDC.) Note that the application does not need to be strong in all categories to be judged likely to have a major scientific impact and thus deserve a high priority score. For example, an investigator may propose to carry out important work that by its nature is not innovative but is essential to move a field forward.

1. Significance. Does this study address an important problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

2. Approach. Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

3. Innovation. Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge or advance existing paradigms, or develop new methodologies or technologies?

4. Investigator. Is the principal investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal

investigator and other significant investigator participants? Is there a prior history of conducting (**fill in area**) research?

5. Environment. Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

PanelRecommendations

If, based on the relevant review criteria, the application is deemed to be of significant and substantial technical and scientific merit, a priority rating is required. The rating can be for the scope of work requested or for an adjusted scope. Three recommendations are possible:

Recommended for Further Consideration: Based on the relevant review criteria, the application is of sufficient merit to be worthy of support. The recommendation may be for the amount requested or for an adjusted amount. The approval period recommended may be for up to three years.

Not Recommended for Further Consideration (NRFC): The application is not of significant and substantial merit. An application may also be recommended for no further consideration when gravely hazardous or unethical procedures are involved, when a supplement to the original successful grant award is deemed to be unnecessary, or if the panel determines that the named principal investigator will not be clearly responsible for the scientific and technical direction of the project. No priority rating is required. These applications are not usually presented to secondary program advisory committees for further consideration.

Deferral: The panel cannot make a recommendation without additional information. This information may be obtained by telephone, by a project site visit, or by the submission of additional material by the applicant. Deferred applications are not presented to a secondary program advisory committee and are usually reviewed again at a future meeting or by a teleconference. Such a recommendation may not be appropriate for a SEP reviewing non-complex applications or in the case of time constraints for making an award within a fiscal budget year.

Rating Procedures

A global priority score range of 1 to 5 is used with 1 representing the highest merit and 5 the lowest merit. Reviewer voting is permitted in 0.1 increments. Panel member votes are added, divided by the number voting and multiplied by 100 to arrive at a three-digit number (152, 279, etc.) that will appear on the first page of the summary statement. The following adjectival equivalents should be prominently displayed on a chart in each meeting room.

Priority Score Range	Adjectival Equivalent
1.0 - 1.4	Outstanding
1.5 - 1.9	Excellent
2.0 - 2.4	Very Good
2.5 - 3.4	Good
3.5 - 5.0	Acceptable

Minority Opinions

A minority opinion is required if two or more reviewers dissent from a majority panel recommendation. This written report should appear as the last item on the summary statement labeled **Minority Report.** If the majority of the panel votes to score a application, and a minority is opposed, all members must record a score. Dissenting members can record a global score of 5. If the majority votes to NFRC a application and a minority is opposed, the application is not scored, i.e., no global scores are required from either majority or minority reviewers.

Budget

Budget recommendations are to be based on the requested direct costs. A budget recommendation, including time and amount, is needed for all applications. The panel should determine whether the requested budget is realistic and necessary for the conduct of the proposed research, well justified, and whether personnel requests and other categories are consistent with the projected scope of work. If budget changes are recommended, there must be specific justifications for any reductions described. Similarly, if the duration of support is modified, a reason must be provided. Any potential overlap with other active or pending support should be noted.

Deleting Part of a Research Project

If any part of a research project does not merit support, the panel may recommend its deletion. The budget should be adjusted accordingly; however, the priority score is based on the pre-modified project. Additionally, reviewers should be reminded to approach these modifications with caution since it is not their responsibility to re-write or re-design an application content.

Research Involving Human Subjects

Safeguarding the rights and welfare of human subjects involved in research activities supported by the Department of Health and Human Services (DHHS) is primarily the responsibility of the

institution that receives the funds awarded. For cooperative agreements involving human subjects in which CDC employees serve as co-investigators, the CDC Institutional Review Board must also review the submitted protocol. However, CDC also relies on panel reviewers to evaluate all applications and applications involving human subjects for compliance with human subject regulations (Code of Federal Regulations, title 45 part 46).

Based on the evaluations of its members, the panel may:

- Favorably recommend the activity without restrictions.
- Favorably recommend the activity, but record expressions of concern to be communicated to the institution and the principal investigator.
- Recommend limitations on the work proposed, the imposition of restrictions, or the elimination of objectionable procedures involving human subjects.
- Recommend the application for no further consideration if the research risks are sufficiently serious and protection against the risks so inadequate as to consider the entire application unacceptable.
- Recommend deferral for resolution of concerns for human subjects protection.

Concerns that members may wish to express about the adequacy of the protections afforded human subjects used in the project should have "Human Subjects" as a Special Note and a human subjects paragraph explaining the concerns after the "Critique" section of the summary statement.

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, CDC relies on its staff, the members of chartered committees and SEP's to review research activities for compliance with the Public Health Service (PHS) policy for the care and use of vertebrate animals. The care and use of vertebrate animals in funded projects must conform to applicable law and PHS policy. A verification of an institutional animal care and use committee (IACUC) review and an institutional assurance are required for applications involving vertebrate animals. IACUC verifications are valid for up to three years. The general intent of the law and policy can be summarized as two broad rules.

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists.

- Animals should not be confined, restrained, transported, cared for, and used in experimental procedures in a manner to inflict any unnecessary discomfort, pain, or injury.

Concerns reviewers may wish to express about animals used in the project should have "Animal Welfare" as a Special Note and an Animal Welfare paragraph explaining the concerns after the "Critique" in the summary statement. When reviewing grant applications that involve especially suitable animal models or particularly effective protocols that conserve animal resources, members are encouraged to note them for inclusion in the "Critique" of the summary statement. Questions may be directed to the Executive Secretary.

With regard to the above policies concerning human subject's protection and animal welfare, no award may be made unless the applicant institution has given the CDC PGO an acceptable assurance of compliance with PHS policy and all concerns or questions raised by the reviewers have been resolved to the satisfaction of the CDC.

Research Involving Hazardous Research Materials and Methods

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the panel in identifying potential hazards, for example, inappropriate handling of biohazardous materials, such as oncogenic viruses, recombinant DNA, chemical carcinogens, infectious agents, and radioactive or explosive material.

If applications pose special hazards, they must be identified and any concerns reviewers may wish to express about the adequacy of safety procedures should have "Biohazardous Material" as a Special Note and a "Biohazardous Material" paragraph explaining the concerns after the "Critique" section of the summary statement.

No awards will be made until all concerns about hazardous conditions have been resolved to the satisfaction of the CDC.

Inclusion of Women and Racial and Ethnic Minorities as Research Subjects

CDC policy requires that applicants, who propose research that involves human subjects and human materials, include minorities and both genders in study populations so that research findings can be of benefit to all persons at risk of the disease, disorder, or condition under study. Applicants must describe the gender and racial/ethnic composition of the proposed study population, and provide a rationale for it in terms of the scientific objectives of the study.

Reviewers will determine if there is appropriate representation of minority groups and both genders in terms of the scientific objectives of the research, and evaluate the rationale and justification provided by the investigator when the representation is limited or absent. If there is

limited representation, or absence of representation, AND the scientific justification for the selected study population is inadequate, reviewers will consider this as a scientific weakness and deficiency in the study design and reflect this in the written review statements and in the assigned priority score. Panel findings and comments on this issue should be included in a section at the end of the "Critique" under a subheading "Gender and Minority Subjects."

Panel Review of Applications

This part of the meeting takes place in two parts. **Part I** involves a triage process (streamlined review) to identify noncompetitive applications. **Part II** involves a full panel discussion of competitive applications.

Part I: Streamlined Review

This is the process by which applications are pre-screened by scientific peer reviewers to identify noncompetitive applications that warrant only very limited discussion by the full panel.

The need for this type of streamlined review is based on the following factors:

- Anticipated receipt of large numbers of applications in response to an announcement relative to available funds.

- By limiting discussion times, the reviewers will be able to concentrate on more complete and competitive applications.

- Fewer personnel are required to conduct the process and complete the paperwork related to a meeting.

A noncompetitive application is an application judged by a scientific peer review group to have scientific/technical weaknesses such that it does not warrant full panel discussion since it should not be considered for funding. The expectation is that the process will eliminate the less meritorious applications received.

A competitive application is an application judged by a scientific peer review group to be of sufficient scientific merit to warrant full panel discussion since it should be considered for funding.

The formal streamlined review occurs the evening before the full chartered external merit review group or SEP meeting. However, the process begins well in advance of the meeting.

Before the meeting:

- Reviewers read all assigned applications.
- Reviewers prepare written reviews for all assigned applications.
- Reviewers send streamlined review recommendation worksheets to DFO for all assigned applications.
- DFO collates all streamlined review recommendation worksheets and faxes copy to chairs.
- Chairs and DFO discuss stramlined review cutoff point (approximately the median).
- Determine a cutoff point usually set to exclude about one-third to one-half of the applications.

Reviewers are asked to complete a form similar to the example below and return it to the Executive Secretary approximately one week or sooner in advance of the meeting.

Streamlined Review Recommendation Worksheet
Reviewer: _____
Panel: _____
Grant #.: _____

Generic Review Criteria	A (Competitive)	B (Possibly competitive)	C (Noncompetitive)
Significance			
Approach			
Innovation			
Progress (if applicable)			
Investigators			
Environment			
Overall Impression			

The Executive Secretary must collate the streamlined review recommendation worksheets response forms and prepare a report similar to the one below for discussion with the Chair prior to the meeting.

Grant #	Primary Reviewer		Secondary Reviewer		Reader		
1723		A		A		A	
1766		A		B		B	
2693		B		B		B	
2694		A		B		C	
2696		B		A		A	
2700		A		A		A	
2702		C		C		C	
2703		C		C		C	
2704		C		C		C	
2705		C		B		A	
2710		B		B		A	
2712		A		B		A	
2713		B		C		B	
2715		C		C		B	
2718		B		C		C	
2719		A		B		B	
2721		C		C		B	

In this example, 5 of 17 applications received noncompetitive grades (C/C) from reviewers. Three more are at the margin, received grades of B and C from the assigned reviewers. What should the threshold be for noncompetitiveness? Should grades of B/C warrant exclusion or inclusion when the streamlined (triage) review process rules are presented to the full panel? The demarcation line can be decided by the Executive Secretary and the Chair or by the panel as a whole. In any case, it is not the final decision since any member of the panel has the right and privilege of requesting that an application be considered competitive and receive a full panel discussion.

Evening Review Meeting

- Chair and DFO discuss streamline (triage) process with reviewers.

- Chair and reviewers agree to streamlined review cut-off values.

- Every application on the meeting agenda is presented briefly (~1 minute) by primary reviewer and secondary reviewer. If there is a disagreement, scores (A,B,C) for each application are noted.

- Panelists vote to include or exclude each application for full review the next day.

- Any panelist can insist on a full review for any application and the request will be honored.

- All applications considered noncompetitive receive an unscored summary statement including reviewers's comments.

The administrative presentation and the streamlined review procedure and the questions and discussion they may generate usually encompass all the business a panel can manage for one evening. It is better to adjourn at this point and start fresh the next morning when a full scientific/technical review of competitive grant applications will begin.

Part II: Formal Review of Competitive Applications:

Full panel review proceeds as follows:

- Discussion: The assigned reviewers will begin by providing their adjectival scores and then the primary reviewer can initiate the discussion of the application followed by other reviewers. All reviewers should be prepared to contribute to the discussion of the applications.

- Recommendation: After the discussion of each application, the chair will ask for a panel recommendation for each application.

- Priority Scoring: Reviewers, on the basis of their individual assessment of merit, and the panel discussion, will privately assign a priority score to each application "Recommended for further consideration." Applications <u>not</u> recommended for further consideration do not receive a priority score.

- Technical Merit: Recommendations should be based solely on the review criteria and the scientific merit of the application, and not on policy or other non-merit considerations.

- Budget Recommendations: After voting and score assignment, reviewers are asked to discuss the budget (time and amount) and provide reasons for any modifications for applications recommended for further consideration. <u>This part of the review recommendation is extremely important.</u>

- Disposal of Materials: All written reviewers' materials should be given to the panel RTA before the close of the session if it has not been previously collected. These materials

should include any changes based on panel discussions, and write ups of all minority reports.

- External Merit Review Group Subcommittee Reports: In the case of meetings of subcommittees of a chartered study section, a member from each subcommittee, usually the chairperson, will report subcommittee recommendations and scores to a plenary session of the study section. The subcommittee Chair will present recommendations for each application reviewed. All members of the external merit group vote on subcommittee reports except those with conflicts of interest.

- The reviewers enter their scores and recommendations on a form similar to the example below. It is probably best to have a single sheet for each application in order to have the staff calculate the panel priority scores in real time.

REVIEWER'S RECOMMENDATION FORM

Application Number	Project Title	Principal Investigator	Individual Panelist (N or R)	Panel (N or R)	Priority Score
R49/CCR12-01	Prevention 1	Doe, J.	R	R	2.3 ----

N=Not Recommended; R=Recommended

Applications for Supplemental Funding

Competing supplemental grant awards may be made when funds are available to support related research work or related activities. Applications should be clearly labeled upon receipt, if necessary, to denote their status as a supplement to an existing award. These applications will be peer reviewed in the same way as a regular grant application.

Site Visits

For the review of larger, more complex applications, information needed to make a recommendation can be gathered by an on-site visit at the applicant institution or a reverse site visit by inviting members of the applicant team to meet with reviewers at the CDC. Site visits may occur before the meeting of a chartered external merit review group or a SEP, if an assigned reviewer or the Executive Secretary recognizes the need for additional information that cannot be

obtained by mail or telephone, or after a formal deferral action at the meeting, if the group is unable to reach a conclusion on the basis of the information available at the meeting. In addition, site visits are often desirable when the application involves complex coordination, as with multi disciplinary, multifaceted program project or center grants, or when the educational and research environment must be assessed, as with many applications for research training grants.

In each case, the Executive Secretary assembles a team of reviewers who are charged with gathering information on specific aspects of the proposed project and reporting their findings and recommendations to a review committee at its next meeting. During the site visit, the reviewers meet with the principal investigator and any other personnel considered central to the application and discuss the areas in question, such as specific procedures, facilities, and administrative arrangements. The report of the site visit team serves as the basis for discussion of the application at the next review meeting. This discussion is led by the members who attended the site visit.

Summary of Review Process

- Each reviewer provides adjectival score prior to their presentation.
- Primary reviewer presentation should take approximately 10 minutes.
- Secondary reviewer presentation should take approximately 5 minutes.
- Reader comments should take approximately 5 minutes.
- General discussion.
- Motion to recommend or not recommend for further consideration.
- Vote on motion: Individual reviewer votes will be for, against, abstain or recusal. Abstentions are discouraged.

If application is recommended for further consideration.

- Appropriateness of budget must be discussed.
- Reviewers must fill in scoring sheet.
- Staff must pick up the scoring sheet and reviewer comments after the discussion of each application.

- Staff calculates application priority scores.
- Summary statement with priority score will be prepared (see next chapter).

If application is not recommended for further consideration:

- Budget not discussed.
- No priority score required.
- Summary statement will be prepared without priority score.
- Minority reports: If two or more panel members vote against the majority a report is required
- Tie votes
    - If motion is “recommended for further consideration” then motion fails.
    - If motion is “not recommended for further consideration” then motion passes.

The Executive Secretary or Chair should remind reviewers to annotate their reviews if they have changed their mind about their written comments during discussion or noted any errors in their written comments. The Executive Secretary or Chair should also request that any reviewer making a significant comment during discussion prepare a brief written statement for inclusion in the summary statement.

REVIEW REMINDERS

STAFF TASKS

- Provide guidance related to the review process.
- Maintain documentation of conflicts of interest.
- Maintain records of attendance.
- Maintain Security/Confidentiality.
- Collect written reviews and computer diskettes.

- Collect scoring sheets, confidentiality and conflict of interest certification forms.

- No undo influence by CIO staff.

- Make master copies of every document (take diskettes). Electronic files or hard copies of documents, and review forms especially are inevitably needed by someone. It is advisable to have them on hand. Take a copy of everything to the review.

EXAMPLE of an EXECUTIVE SECRETARY TO DO LIST for GRANT REVIEWS

1. Attendance sheet for reviewers handed out **(EACH DAY)**.

2. Conflict of interest statement to be signed first day.

    - If there is a potential conflict with grant under discussion, reviewer must be recused, that is, the reviewer must excuse himself from the panel room during discussion of that grant.

3. Mention need for confidentiality.

    - No discussion outside room.

    - No conversation with grant applicants serving on other panels after meeting.

4. Evening before full review.

    a. 6:30-7 p.m. — introductions with all reviewers.

    b. 7-9 p.m. — reviewers to each panel for grant review.

    c. Streamlined (triage) review begins — Criteria for full review set at [include cut-off time here] or better (if one reviewer feels strongly after discussion that a grant should be fully reviewed, then it will be reviewed).

    d. Decision by Chair if any grants need additional readers.

Day of full review.

a. Have reviewers sign attendance sheet — necessary to be paid. Reviews should begin promptly at 8:00 A.M.
b. Complete streamlined (triage) review if not yet completed.
c. General reviews begin after streamlined (triage) review, in order listed.
d. Executive secretary or Chair reads reviews from those reviewers not in attendance or from supplemental reviewers.

e. Time for each review should be as follows: 10 minutes for primary reviewer, 5 minutes for secondary reviewer, several minutes for reader, 5-10 minutes for general discussion. Each reviewer must provide an adjective (outstanding, excellent, very good, good, or acceptable) describing the quality of the grant prior to their presentation.

f. Robert's Rules of Order will be followed.

g. After discussion, a motion for "recommended for further consideration" or "not recommended for further consideration" will be made and then seconded. [One can also move that an application be considered a streamlined (triage) application, that is unscored, if it appears that it would not be recommended for further consideration]. There will then be further discussion of the motion, and the Chair will call for a vote. One can vote for the motion, against the motion, abstain, or be recused. If the motion passes and two or more vote against the motion, then a minority report must be written (one or two additional paragraphs). If the motion fails, then a motion must be made for the opposite recommendation. If a motion for "recommendation for further consideration" results in a tie vote, then that motion fails. If a motion for "not recommended for further consideration" results in a tie vote, then the motion passes.

h. If the grant is recommended for further consideration, the appropriateness of the BUDGET is then discussed. Finally, the reviewers fill in their scoring sheet. Only grants that are recommended for further consideration will be presented to secondary review committee.

I. A member of the staff picks up the scoring sheet after each grant is scored. Also, they will pick up the reviews of each reviewer and give them to the recorder.

POST-MEETING EVALUATIONS

- Feedback to Improve Peer Review Process: As a concluding item of business at each peer review meeting, it is beneficial to request that reviewers comment on the review process. From the dialogue about what went well, what did not go so well, and suggestions for improvements, many useful ideas can result.
- Staff Evaluations of Reviewers and Chairs: For future reference, it is very worthwhile to evaluate the panel members; in some cases there are those that perhaps should not be selected for future service of this type.

PERFORMANCE EVALUATION FACTORS FOR CHAIRS

EVALUATION FACTOR	Yes/No
Comes to meeting well prepared	
Follows the prescribed peer review procedures	
Exhibits good leadership abilities	
Conducts panel proceedings in a fair, objective and effective manner	
Summarizes accurately panel discussions of strengths and weaknesses of applications	
Exhibits cooperativeness in working with Executive Secretary and staff	
Assists Executive Secretary in conducting organized debriefing at conclusion of panel meetings	

SCIENTIFIC REVIEWER PERFORMANCE EVALUATION FACTORS

EVALUATION FACTOR	Yes/No
Comes to meeting prepared	
Prepares good written material on assigned applications	
Participates in panel discussion of other than assigned applications	
Opinions respected by other panel members	
Articulates well	
Abides by prescribed peer review procedures	
Gets along well with panel member colleagues and staff	
Completes all work assignments	

CHAPTER VI
First Level of Review: Post-Meeting Activities

CHAPTER CONTENT

Summary Statements

Summary statements are the official agency record of the initial peer review deliberations related to each competitive application received. Immediately after the review meeting, the Executive Secretary prepares a summary statement for each application. These summary statements, which are based on a combination of the reviewers' written comments and additional information from the discussion during the meeting, become the official documents concisely describing the deliberations of the review panel. Summary statements include the recommendations of the panel, a recommended budget, and notations of any special points, such as research that is especially creative, innovative, or high-risk. A separate minority critique must also be provided if two or more members voted against the majority recommendation. Individual reviewers' written comments and other notes are not retained after the summary statements have been prepared.

Aspects of an application other than scientific or technical merit, which the Executive Secretary or panel may consider important enough to be brought to the attention of the sponsoring CIO, are usually included in the summary statement and are referred to as Administrative Notes. Examples, may include possibility of scientific overlap of the current submission with other active support, or duplicate submissions to another agency.

Summary statements have numerous and important uses.

- Members of second tier advisory committees use summary statements as the main source of information about applications and as the primary basis for their recommendations concerning funding.

- Center staff use summary statements as guides in the future management of awards.

- After the review process is complete, Center staff send each principal investigator a copy of the summary statement with the priority score displayed. The summary statement is therefore important to investigators in reassessing, adjusting, or improving their research projects, as well as in preparing future applications.

- Summary statements, whenever appropriate, can provide background information to peer review members relative to a revised, supplemental, or competing continuation application submitted in the future.

Reviewers have the responsibility to provide sufficient evaluative information to ensure summary statements of high quality.

Summary Statement Preparation

The preparation of summary statements in final form is the responsibility of the Executive Secretary of a review panel. Assistance with this task can be obtained by recruiting experienced professional help from individuals designated as Recorders. It will take the recorders a reasonable amount of time to generate draft summary statements depending on workload and deadline constraints. The recorders should receive hard copies of the reviewers' written comments, their diskettes, and other relevant notes that the Executive Secretary may have. A copy of all this material should be retained by the CIO staff. After hard copies of the draft summary statements and copies on diskettes have been received, the panel Executive Secretary must review their content for appropriateness and editorial changes. Keep one as a master file copy until the summary statements are finalized. These changes are made on the diskette(s) and then reprinted.

After all summary statements are in final form, the reviewers' written comments and the Executive Secretary's and Recorders' notes should be disposed of to maintain their confidentiality. In no case should such documents and disks be placed in an official grant file. The same is true for assignment sheets related to a peer review meeting or individual reviewer score sheets or any other staff notes related to the review. The reason for this precaution is that an applicant has the right to review the content of their official grant file under the provisions of the Privacy Act. On the other hand, the agency has an obligation to protect the privacy of individual reviewers and their comments and votes. Two copies of each final summary statement should be made and a list of the review panel participants stapled to the back of each as well as an explanation of the scoring system. These should be sent to PGO. The PGO staff will send one copy out to the principal investigator and keep one copy for their records.

Summary Statement Content and Format

The instructions to reviewers for preparing their written comments should parallel as much as possible the format of the summary statement that the CIO and its staff desire to have as a final end product of the peer review. A current example is described below but should be modified in line with the specific review criteria published in an RFA. The criteria below are those being used by the study sections at NIH and several CIOs at CDC for the review of investigator-initiated R01 research

applications. The requirements of the Centers at CDC may be quite different and therefore adjustments can be made easily. Examples of the review comment and summary statement forms are shown as Exhibits VI-1 through VI-3, pages VI-5 through VI-9.

OTHER POST MEETING ACTIVITIES:

MEETING MINUTES: These are prepared by the Executive Secretary or the Center Committee Management Specialist. Copies of the draft are sent out to various division staff such as Director, Grants Branch Chief, etc., and perhaps to the panel Chair for comments and edits. After all revisions have been made, the Executive Secretary should finalize the minutes.

THANK YOU LETTERS: These should be prepared by the Executive Secretary and sent to each reviewer who participated in the review. A sample letter follows that can be modified as required by the specific CIO involved. A sample letter is provided in Exhibit VI-4, page VI-11.

PAYMENT OF CONSULTANTS: Send PGO a list of those who were present and how many days they are to be paid an honorarium. For a chartered committee, funds can be made available for its support via a grant to the committee Chairperson. This grant, also referred to as a Scientific Review and Evaluation Award (SREA), consists of funds automatically deposited in an interest-bearing account and is the mechanism for payment of study section expenditures including travel, consultant fees, per diem of members and special ad-hoc reviewers, meeting room space, workshop costs and publication of workshop proceedings.

Several individuals play a role in the chairman's grant. After appointment, the chairperson manages the fund. Reviewers' travel vouchers, which have been certified by the Executive Secretary as to the correct number of consultant days served and processed by PGO for accuracy and validity, are forwarded to the chairperson for payment. Travel advances, not to exceed the common carrier rate, may also be arranged by members through the Executive Secretary and PGO before the meeting. The chairperson's secretary, or a designated individual, can prepare checks for payment just short of signature, and may also be assigned responsibility for reconciling the records on behalf of the chairperson.

Reimbursement for travel, per diem, and professional services for members of SEPs are processed and made by the program office using the SEP. The Designated Federal Official will submit a requisition through their Administrative Office for a purchase order for members to receive their honoraria.

PERMANENT RECORD OF EACH PANEL MEETING: Certain lists should be generated and documents compiled in a loose leaf binder as a permanent record of the review. Examples of items to include are:

Several tables with information about the applications received. The tables can be arranged as follows.

Table 1 - Application Number, Institution, Title, Panel, PI.
Table 2 - Principal Investigator, Application Number, Institution, Title.
Table 3 - Panel, Application Number, Institution, Title, Principal Investigator.
Table 4 - Table 1 plus recommendation and priority score.
Table 5 - Table 2 plus recommendation and priority score.

Other documents to include are a copy of the program announcement, a set of summary statements, the minutes of the meeting to include a roster of the review panel, attendance sheets, conflict of interest forms, any pertinent letters or memos that were prepared. The latter may relate to letters of invitation and confirmation with dates to reviewers, memos that accompany mailings to reviewers with instructions for preparing written comments, thank you letters, any relevant transmittals to the PGO and other miscellaneous material related to the review that may prove useful in the future.

Exhibit VI-1

FORM FOR PREPARATION OF REVIEWER COMMENTS

Application Number: Principal Investigator:

Reviewer/Reader: Date:

Project Title:

DESCRIPTION (primary reviewer only): Please provide a non-evaluative abstract of the program presented in the grant application. If the abstract in the application is accurate, you may use it verbatim and attach it to this document.

SIGNIFICANCE: Does this study address an important **(fill in area)** problem? If the aims of the application are achieved, how will scientific knowledge be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

APPROACH: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics? Does the project include plans to measure progress toward achieving the stated objectives? Is there an appropriate work plan included?

INNOVATION: Does the project employ novel concepts, approaches or methods? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

PROGRESS: For competitive renewals and supplemental requests: Has progress during the prior project period been satisfactory?

INVESTIGATORS: Is the principal investigator (PI) appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the PI and other significant investigator participants? Is there a prior history of conducting **(fill in area)** research?

ENVIRONMENT: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of the unique features of the scientific environment or employ useful collaborative arrangements? Is there evidence of institutional support? Is there an appropriate degree of commitment and cooperation of other interested parties as evidenced by letters detailing the nature and extent of the involvement?

WOMEN AND MINORITIES: Are there adequate plans to include women, minorities and their subgroups as appropriate for the scientific goals of the research? Are the plans for recruitment and retention of subjects satisfactory?

HUMAN SUBJECTS: Are there any risks to human subject participants in the research (either medical, sociological, legal, or psychological)? Are there adequate safeguards to protect their privacy and welfare?

ANIMAL WELFARE: Is there adequate protection for the welfare of vertebrate animals in the research? Are the numbers and species of animals appropriate?

BIOHAZARDS: Are there any hazardous procedures involved that would affect the safety and well being of research subjects or investigators?

BUDGET: Is the requested budget reasonable? Is the duration of support requested appropriate? If modifications in either case are recommended, please provide specifics along with reasons for any modifications.

SUMMARY AND RECOMMENDATIONS: Summarize the strengths and weaknesses of the application. Provide the key reasons for your recommendation.

Exhibit VI-2

EXAMPLES OF SUMMARY STATEMENT OUTLINES

SUMMARY STATEMENT
(Privileged Communication)

ANNOUNCEMENT TITLE AND NUMBER

Application Number:

Review Group:

Meeting Dates:

Project Title:

Principal Investigator:

Institution:

City, State:

RECOMMENDATION: (Recommended for further consideration **OR** Not Recommended for further consideration **OR** omitted if application is Unscored)

PRIORITY SCORE: 100-500 **OR** Unscored (if streamlined) **OR** Omitted if Not Recommended for further consideration

Human Subjects, Animal Welfare and Biohazards: (Concerns **OR** No Concerns **OR** Comment)

Women and Minority Inclusion: (Concerns **OR** No Concerns **Or** Comment)

Year	**Direct Cost Requested:**	**Year**	**Direct Cost Recommended:**
01	$xxx,xxx	01	$xxx,xxx
02	$xxx,xxx	02	$xxx,xxx
03	$xxx,xxx	03	$xxx,xxx

SUMMARY (**if scored**): Brief description of the project with specific research aims and objectives. Also include pertinent discussion during full review and brief summary of overall strengths and weaknesses as noted by the review group.

SUMMARY (**if unscored** this is standard language that be used for each triaged application): The Committee considers each application and initially determines relative overall scientific merit. Applications regarded as having the highest merit are assigned a priority score; others remain unscored. This application did not receive a score. However, a compilation of the reviewer's comments are provided below without significant modification.

DESCRIPTION:

SIGNIFICANCE:

APPROACH:

INNOVATION:

PROGRESS:

INVESTIGATORS:

ENVIRONMENT:

BUDGET:

GENDER and MINORITY INCLUSION: If applicable or if concerns are raised.

HUMAN SUBJECTS: If applicable or if concerns are raised.

ANIMAL WELFARE: If applicable or if concerns are raised.

BIOHAZARDS: If applicable or if concerns are raised.

MINORITY OPINION: If applicable.

There are two choices for how the summary statement can be constructed following the above format: (1) The primary individual reviewer's comments can be included in its entirety under a subtitle REVIEWER A followed by a similar insertion of comments from REVIEWER B and then from REVIEWER C (or READER) if applicable, or (2) the comments from each of the reviewers can be blended under each of the format headings above.

For streamlined applications, the first option seems the more appropriate one because there is little or no other relevant material to include since no extended discussion of the application occurred. On the other hand, the converse is true for competitive applications that receive a more complete discussion. Therefore, option 2 seems more appropriate for non-streamlined applications.

Another example of a summary statement format more structured to criteria published in a RFA follows.

Ehibit VI-3

SUMMARY STATEMENT FORMAT

SUMMARY STATEMENT
(Privileged Communication)

Application Number
R49CCR-000000-01

Review Group:

Meeting Date:

Institution:

City, State:

Principal Investigator:

Project Title:

RECOMMENDATION: Recommended for further consideration **PRIORITY SCORE:** 000

OR

RECOMMENDATION: Not recommended for further consideration

OR

RECOMMENDATION: Unscored

Human Subjects, Animal Welfare and Biohazards: No Concerns

OR

Human Subjects, Animal Welfare and Biohazards: Concerns or Comment

Year	Direct Cost Requested:	Year	Direct Cost Recommended:
01	$000,000	01	$000,000
02	$000,000	02	$000,000
03	$000,000	03	$000,000

RESUME:

PROGRAM REQUIREMENTS and PRIORITIES:

EVALUATION OF PAST PROGRESS:

RESEARCH OBJECTIVES:

BACKGROUND INFORMATION:

SIGNIFICANCE:

ORIGINALITY:

RESEARCH HYPOTHESES:

RESEARCH DESIGN:

EVALUATION:

PERSONNEL:

COOPERATION:

BUDGET:

FACILITIES:

OTHER CONSIDERATIONS:

Exhibit VI-4

Sample Thank You Letter

Date:

Dear:

Thank you for participating in the recent peer review of applications received in response to RFA **(INSERT NAME AND NUMBER)**. Your written and verbal opinions made a valuable contribution to panel discussions, and were very much appreciated. As you know, the summary statements resulting from panel discussions of written reviews are extremely helpful to many applicants who are able to improve their efforts because of the time and attention you and your panel colleagues give to their applications. As they cannot thank you directly, I want to transmit to you their appreciation as well. The summary statements are also an essential document considered by the **(INSERT NAME OF CIO)**. Secondary Advisory Committee in making funding recommendations. In that regard, a list is attached of those applications that were eventually funded.

Please sign the enclosed voucher and return it in the attached envelope to expedite payment of your honorarium and travel expenses. If you have any questions or comments, please don't hesitate to call me or **(INSERT NAME)**. We can be reached at **(INSERT PHONE NUMBER)**. I look forward to working with you again in the future.

Sincerely yours,

Executive Secretary

CHAPTER VII
Second Level of Review

CHAPTER CONTENT

After applications are reviewed by the appropriate SEP or chartered committee, those that are recommended for further consideration are presented for programmatic review to a Secondary Review Committee. This model can be adapted easily for use by other CIOs.

PRE-MEETING ACTIVITIES

In the case of a chartered committee, a notice of a meeting must be published in the Federal Register. Along with the date, time, and place, the purpose of the meeting is included using procedures previously described in Chapter III.

PREPARATIONS FOR SECONDARY REVIEW MEETINGS

A. Set meeting date

1. Contact participants two months before the review is to take place.

2. As early as possible, arrange for the meeting place.

3. Confirm that letters are sent to reviewers confirming their attendance, giving particulars, and enclosing certain background materials. These letters are prepared and sent by the appropriate CIO official.

4. Prepare material in binders (Prepare copies for each review cycle. Prepare copies for each participating reviewer as well as for each CDC program staff member who will be attending the review meetings.)

B. At the convenience of staff (can be done before primary review)

1. Assemble, duplicate, and collate the following:

- Table of Contents.
- Primary Review participant rosters.

- Secondary Review participant rosters.
- Federal Register Announcement for appropriate fiscal year.
- CIO Information of interest.

2. Prepare and insert necessary tabs.

C. Arrange for copies of the abstracts of **applications not recommended for further consideration** applications to be copied, hole-punched, and inserted in the binder.

D. Generate the necessary tables for the binder:

Table	Topic
C1	Research Grant Applications, by discipline or area of interest, Fiscal Year, and Funding Status
C2	Currently Funded Extramural Research Projects by discipline or area of interest, Current Fiscal Year
C3	Currently Funded Research Topics by Research Agenda Topics
D1	Applications Recommended for Further Consideration in Rank Order by Priority Score, by Principal Investigator **[SHOWING TOTAL COST BY YEAR]**
D2	Applications Unscored, by Principal Investigator, by Panel
D3	Applications Recommended for Further Consideration, by Research Area, by Research Agenda Topics
D4	Applications Recommended for Further Consideration, by Populations of Special Interest
D5	Applications Recommended for Further Consideration by Other Topics of Special Interest

E. Staff Recommendations.

F. As soon as final summary statements are prepared (two week prior to meeting), arrange to have a sufficient number of copies made **(applications recommended for further consideration only)**, hole punched, and inserted in the binders.

G. Arrange for delivery of the books to the participants **at least one week prior** to the review meeting, as follows:

- One to each advisory committee member.

One for each CIO staff member, including grants staff, executive secretaries, directors, and designated others.

- Two copies for the Assistant Director for Science, [CIO Name], and the CDC.

- Two copies in reserve for those last minute unforeseen incidents, and unplanned events.

PROGRAMMATIC REVIEW BY APPROPRIATE SECONDARY REVIEW COMMITTEE

Review criteria to be considered for applications received in response to Program Announcements, RFAs, or supplements to existing RFAs include:

- The results of the peer review.

- The significance of the proposed activities as they relate to national program priorities and the achievement of national objectives.

- National and programmatic needs and geographic balance.

- Funding levels within budgetary considerations. The committee will establish annual funding levels as detailed under the heading, **AVAILABILITY OF FUNDS**. In addition, a separate list of applications warranting support should be prepared in the event funds become available.

PREPARATION OF MEETING MINUTES

The basic information required by the Committee Management Office should be included analogous to that prescribed for a chartered merit review group or SEP. In addition, there usually are several agenda items of importance discussed aside from the programmatic review of grant applications. The highlights should be captured along with recommendations and included in the minutes.

STAFF ACTION: NON-COMPETING APPLICATIONS FOR CONTINUED FUNDING

Non-competing continuation awards within the project period are made on the basis of the availability of funds and the following criteria applied by the CIO program staff:

- The accomplishments of the current budget period and assurance that the applicant's objectives as prescribed in the yearly work-plans are being met.

- The objectives for the new budget period are realistic, specific, and measurable.

- The methods described will clearly lead to achievement of these objectives.

- The evaluation plan allows management to monitor whether the methods are effective by having clearly defined process, impact, and outcome objectives, and the applicant demonstrates progress in implementing the evaluation plan.

- The budget request is clearly explained, adequately justified, reasonable, and consistent with the intended use of grant funds.

- Progress has been made in developing cooperative and collaborative relationships with injury surveillance and control programs implemented by state and local governments and private sector organizations.

PURGING APPLICATIONS

Applications that are either not recommended for further consideration or not funded are purged thirteen months after the secondary review for that cycle.

GENERIC CHECKLIST

The above generic criteria and meeting preparation procedures can be modified to fit the requirements of any CIO as needed or indicated by programmatic considerations specific to a particular CIO. A generic list of factors to be considered in conducting secondary programmatic reviews are:

- The need for a senior disinterested federal staff or members of a chartered Advisory Committee

- Criteria to be used by secondary review committees should be noted in the RFA, e.g.:

    - Results of peer review

    - Programmatic interests and balance

    - Geographic balance

    - Budgetary considerations

    - Others as deemed important by a CIO

- Factors usually not for consideration:

    - Scientific and technical merit

- Project Officer should prepare staff recommendations.

- Justification should be provided for the record if applications are by-passed in the order of merit from the SEP peer review.

- Secondary review recommendations are sent to the funding official for final approval. This is the CIO Director.

CHAPTER VIII
Important Policy and Ethical Consideration

CHAPTER CONTENT

Chapter Overview

This chapter is limited to the more practical, ethical issues that must be clearly understood by CDC staff. It encompasses a variety of policies that fall within the various stages of the grant process. Prominent among these are matters related to conflict of interest. In the case of members of peer review panels and secondary advisory panels, there are three broad categories of conflicts.

1. Advisory committees cannot review an application from one of its own members. While members of peer review panels may submit proposals, their proposals must be reviewed by another panel or sub-panel.
2. Members of either type of advisory panel must recuse themselves from the discussion of proposals submitted by others at their own institutions or from institutions in which they or any family members have a financial interest.
3. Members of either type of advisory panel must recuse themselves from the discussion of proposals from close professional associates or—in many cases—from former collaborators or students.

Some of the obvious situations are provided below in greater detail but many times common sense and good judgement are required to ensure that panel members avoid any real or apparent conflicts of interest. Likewise, members of the CDC staff are held to the same standards. They should be careful to recuse themselves from any decisions or involvement with proposals from institutions in which they or members of their family have a financial interest (e.g., shares of stock) or from present or former close professional collaborators or associates.

An awareness of provisions of the Privacy Act and the Freedom of Information Act is mandatory. Applicants have a right of access to their own grant files by invoking the Privacy Act. This means that the grant file should only contain official documents related to the review and processing of a proposal. Individual reviewer's comments, individual score sheets, panel member assignment sheets, staff member notes should not be retained. In the case of the Freedom of Information Act, members of the public can request to see information in a grant file related to any funded proposal. Before releasing such information, however, it is essential to notify the awardee and to identify any private information, e.g., salary or proprietary material that should not be made available.

Another broad and sensitive group of issues and policies are specifically related to the protocols and content of grant proposals. It is well known that an Institutional Review Board (IRB) at the applicant institution must approve research involving human subjects. However, this does not preclude responsibility of reviewers of proposals to identify human subject problems or unacceptable standards of practice that may be present. In terms of protocols involving human subjects, there are also mandatory requirements that women and minority subjects are included or a compelling justification offered for not doing so. In terms of protocols involving animals, reviewers of grant proposals have an obligation, notwithstanding approval by an Institutional Animal Care and Use Committee (IACUC), to determine if animal welfare has been carefully and appropriately considered. The same principle holds true for any biohazards involved with research protocols that may be detrimental to the health and well being of researchers or subjects, e.g., exposure to excess radiation, infectious agents, etc. A more detailed description of these issues is presented below.

Conflict of Interest

Adherence to real and apparent conflict of interest policies is mandatory. Unfortunately, these are not always straightforward. Therefore it is incumbent on staff to become thoroughly familiar with the rules and to inject common sense and good judgement when interpretations and unclear situations are confronted. What follows are descriptions of the hard and fast rules, as well as situations which fall into the gray area that many times are more difficult to resolve.

Peer Review Panel Member Conflicts

Disqualifying Conflicts for Members of Peer Review Panels:
A peer review panel may not review an application from one of its own members who is serving as the principal investigator or is in any way deriving financial or other benefit from the proposed request. In addition, the same rule applies if a member's spouse, parent, or child is involved in an application. In the case of fellowship applications in which a member is named the sponsor or current Ph.D. mentor, the member's peer review panel may not review them. A peer review panel may not review an application from a for-profit organization if one of the members is an owner or officer. These types of conflicts, with direct involvement or association of peer review panel members in an application are usually resolved before a review meeting by assignment of the application to other panels where no such conflicts exist.

An application from a close professional associate of a peer review panel member may also be disqualifying and be better reviewed by a different panel. The decision is based on:

1. The recency, frequency, and strength of the working relationship between the member and the associate as reflected, for example, in publications.
2. The determination of whether the member has a self-interest or tangible involvement in the application.

For example, a member and principal investigator, who are no longer at the same institution, may still be publishing data generated when they were laboratory colleagues. The member may not be otherwise named in the application, has no self-interest, or tangible involvement in, the application, but may appear as a joint author in the biographical sketch. However, because of the appearance of conflict of interest, the application should be reviewed by a different panel.

Recusal Conflicts Requiring Members of Peer Review Panels to Absent Themselves from the Meeting:

- *Limited Member Involvement*: The member's peer review panel may review those applications in which no tangible benefits accrue and involvement is limited to being a provider of routine services, cell lines, reagents, or other materials; or writing a letter of reference. In these cases, however, the member must be absent from the room during the review.

- *Application from a Close Professional Associate*: In the case of an application from a former close professional associate of a peer review panel member, if collaborative efforts are no longer active and have not been for a minimum of 3 years, the application can be reviewed by the member's panel. However the member must leave the room for the discussion of the application. The strength of the continued association and all other facts must be carefully weighed before a decision is made whether an application is acceptable for review by the member's panel.

- *Fellowship and Other Training Applications*: During the discussion of applications, members from the sponsoring institution (i.e., where the training will take place), as well as members who provide reference letters for applicants must leave the room. Members also must leave

the room if a fellowship applicant was, or is, a doctoral student in their department, even if the applicant was not the member's student.

- *Institutional Conflicts*: A member must leave the room when an application submitted by someone else at his/her own organization is being discussed. The term "own organization" includes the entire system in which the member is an employee, consultant, officer, director, or trustee or has a financial interest; or with which the member is negotiating or has any arrangement concerning prospective employment. However, there is an exception for certain multi campus institutions. In such cases, it has been determined that the interest involved is too remote or too inconsequential to affect the integrity of a review of a proposal from one of the multi campus state institutions (listed in table below), where the interest consists solely of employment as a faculty member at a separate campus of the same multi campus institution.

- *For-Profit Organizational Conflicts*: Reviewers must leave the room during discussion of an application in which they are not involved but may be consultants or employees in the organization submitting the application. This is also true regardless of the location of the principal investigator in any of the geographically separated facilities of the applicant organization. Multi campus rules do not apply to for-profit organizations. Reviewers also should leave the room during discussion of an application if their presence would give the appearance of a conflict of interest.

Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory, or from an organization that is in commercial competition with the reviewer's organization. Additionally, reviewers from the "*for profit*" sector should not evaluate applications that involve material of commercial interest to their company.

- *Scientific and Professional Enmities*: Members should recuse themselves from reviewing a proposal from a scientist with whom the member has had longstanding differences that can reasonably be viewed as affecting the member's objectivity.

- *Former Students*: It is probably best for members to recuse themselves from the review of applications from former students regardless of time intervals because of previous collegial relationships.

- *General Admonitions*: Members also are urged to avoid any actions that might give the appearance that a conflict of interest exists, even though they may not believe there to be an actual conflict of interest. Thus, for example, a member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, or a close personal friend. Judgment must be applied on the basis of recency, frequency, and strength of the working relationship between the member and the principal investigator, as reflected, for example, in joint publications. Another example is the review of a project, which closely duplicates work ongoing in the member's laboratory. At times the members will seek guidance on whether or not a conflict exists. In very doubtful situations, the way to resolve

the question is to ask the member directly if he/she can be objective. If the answer is positive, there is no need for the member to leave the room.

Rules Related to Multi Campus Organizations and Multiple State-Supported Systems:

According to the Federal Register, Vol. 51, No. 80, April 25, 1986, subsystems within 22 states are considered separate organizations or are multi campus institutions where conflict of interest *prohibitions do not* apply for the purposes of the conflict-of-interest statute. Universities within the states below are understood to be sufficiently distinct from each other, or that interest is considered so remote that no conflict of interest exists that would preclude a peer review group member from one of those entities from reviewing grant applications or contract proposals from another entity. Thus, a member from Illinois State University may review applications from the University of Illinois or Southern Illinois University. In addition, for some state systems, such as the University of California system, each campus (University of California at Berkeley, University of California at Davis, etc.) is considered a separate organization. These are multi campus institutions within the state.

Subsystem Organizations and Multi campus Institutions Considered Separate for the Purposes of Conflict of Interest Statute

The following institutions are considered separate organizations or institutions where conflict of interest prohibitions do not apply:

ALABAMA: The University of Alabama system, consisting of the University of Alabama, University of Alabama in Birmingham, the University of Alabama in Huntsville, and other Alabama State-owned institutions of higher education.

CALIFORNIA: The University of California campuses, the California Community Colleges, and the California State Universities and Colleges.

COLORADO: The University of Colorado, the system consisting of Colorado State University, the University of Southern Colorado, Fort Lewis College, and other Colorado State-owned institutions of higher education.

CONNECTICUT: The University of Connecticut, Connecticut State University, the Connecticut Technical Colleges, and the Connecticut Community Colleges.

ILLINOIS: The University of Illinois, Illinois State University, Western Illinois University, Southern Illinois University and the Illinois Community Colleges.

INDIANA: The Indiana University system, consisting of eight universities on nine campuses, with the exception of the system-wide schools; the School of Business, the School of Dentistry, the School of Medicine, the School of Nursing, and the School of Public and Environmental Affairs, and the other Indiana State-owned institutions of higher education.

IOWA: The University of Iowa and Iowa State University.

KANSAS: The University of Kansas, Kansas State University, Wichita State University, Fort Hays State University, Pittsburgh State University, and the Kansas Technological Institute.

LOUISIANA: Louisiana State University and other Louisiana institutions of higher education.

MASSACHUSETTS: The University of Massachusetts and other Massachusetts State-owned institutions of higher education.

MICHIGAN: The University of Michigan, Michigan State University, and Wayne State University.

MINNESOTA: The University of Minnesota, the Minnesota State University system, and Minnesota Community College System.

MISSOURI: The University of Missouri and other Missouri State-owned institutions of higher education.

NEBRASKA: The University of Nebraska system, consisting of the University of Nebraska-Lincoln, the University of Nebraska at Omaha, the University of Nebraska Medical Center, and other Nebraska State-owned institution of higher education.

NEW YORK: The campuses of the State University of New York and the City University of New York system.

NORTH CAROLINA: The University of North Carolina, North Carolina State, and other North Carolina State-owned institution of higher education.

OREGON: The Oregon system of higher education, consisting of the University of Oregon, Oregon State University, Oregon Health Sciences University, Portland State University, Western Oregon State College, Southern Oregon State College, Eastern Oregon State College, and Oregon Institute of Technology.

PENNSYLVANIA: Pennsylvania State University, the University of Pittsburgh, Temple University, Lincoln University, and the other State-owned colleges and Universities in Pennsylvania.

TENNESSEE: The campuses of the University of Tennessee.

TEXAS: The separate universities comprising the University of Texas system, Texas A&M system, Texas State University system, East Texas State University, Stephen F. Austin State University, West Texas State University, Midwestern University, University system of South Texas, North Texas State University, Texas Southern University, Texas Woman's University, Lamar University system, Texas Tech University, University of Houston system and Pan American University.

UTAH: The University of Utah and Utah State University.

WISCONSIN: The separate universities comprising the University of Wisconsin system.

Each of the Harvard-affiliated organizations is considered a distinct and separate entity, so that persons from one are not in conflict if reviewing applications from another, provided they have no professional or personal relationships with the other institution. Thus, a member from Massachusetts General Hospital can review an application submitted from Beth Israel Hospital. **a**s long as there are no personal, professional, or business relationships. However, staff must be alert to the possibility of reviewers having multiple institutional affiliations. For example, a reviewer from Brigham and Women's Hospital who also holds a Harvard Medical School appointment is in conflict with both institutions.

Harvard affiliated institutions include:

Beth Israel Hospital
Brigham and Women's Hospital
Cambridge Hospital
Center for Blood Research
Children's Hospital
Dana Farber Cancer Institute
Forsyth Dental Center
Harvard Community Health Plan
Massachusetts Eye and Ear Infirmary
Massachusetts General Hospital
Massachusetts Mental Health Center
McLean Hospital
Mount Auburn Hospital
New England Deaconess Hospital
New England Regional Primate Research Center
West Roxbury/Brockton Veterans Administration Center

Howard Hughes Medical Institute: Reviewers who are supported as investigators of the Howard Hughes Medical Institute may not review applications submitted by other investigators who receive support from this institute.

Veterans Administration and NIH: Rules similar to HHS rules regarding conflict of interest apply to the Veterans Administration (VA). Different VA organizations are considered separate for purposes of conflict of interest.

The situation is different for the institutes and centers at NIH. They are, for the most part, located on one campus and there is much collaboration and communication among the research scientists of the various institutes and centers. Thus, the NIH institutes and centers are considered as a single campus organization and reviewers from NIH are in conflict and must recuse themselves from the review of any NIH application.

Blanket Waiver of Conflict

On October 18, 1999, a blanket waiver of conflict of interest for peer review consultants was granted. The policy states that all separate organizational components/schools of multi-component academic institutions, hospitals, health centers, and research institutes may be considered sufficiently independent such that an employee of one component can review an application from another component without conflict of interest, so long as any other real or apparent conflict of interest is resolved. This waiver is in addition to all of the above. For example: (1) Georgia Tech. and the U. of Georgia are considered separate institutions; (2) the campuses of the U. of Florida, Florida State, and U. of South Florida are considered separate; (3) the Johns Hopkins Bayview Medical Center and the School of Arts and Sciences, Homewood Campus, are separate components; (4) the Johns Hopkins School of Arts and Sciences and of Engineering, Homewood Campus, are separate components; (5) the Departments of Biology and Chemistry within the School of Arts and Sciences are NOT separate components. In the future, other blanket waivers may be established; in the interim and subsequently, other waivers may still be granted on a case-by-case basis. State systems other than higher education systems, such as the state bureau of health or elements of the state hospital system, are separate entities not in a conflict of interest situation with each other or with the state higher education system.

Program Advisory Panel Member or Consultant Conflicts

Applications reviewed by peer review panels within an "eligibility for funding range" are considered by senior advisory committees. Such applications already have been scientifically evaluated based on published review criteria and given an appropriate priority rating. What remains to complete the peer review process is a programmatic review to determine the relevance of the various research and training applications to the mission of the CDC Center.

An unequivocal requirement of all participants is to avoid both actual and perceived conflicts of interest that arise when a member may be viewed as being in a position to gain or lose personally, professionally, or financially from a proposal under consideration. Program advisory committee members or other consultants should not be permitted to submit grant applications if they have been involved in decisions related to program priorities, investment strategy, or program announcement of a program initiative and thus could be viewed as being at a competitive advantage in obtaining support.

For the programmatic review of peer reviewed proposals, if members feel they have or may appear to have a conflict of interest on an assigned proposal, they must notify the staff immediately so that the proposal may be reassigned to another reviewer. If a conflict arises during the meeting itself, members must recuse themselves from the proceedings for the given proposal, excuse themselves from the meeting for the period the conflicting application is being reviewed, and abstain from voting on that proposal. Members themselves bear the responsibility to be vigilant in avoiding actual or perceived conflicts of interest. This is especially true if a very large number of applications is under consideration. To briefly summarize, the most prominent reasons for conflicts at the programmatic secondary review level are:

- The member holds an appointment at the applicant institution.
- The member has a close personal and/or professional relationship with the applicant(s).
- Other rules and situations described above that require members to absent themselves from the meeting during the discussion of specific applications include but are not limited to:

    - **A member is named in the proposal or who expects to be invited to participate in the research in any way.**
    - A member's spouse, parent, child, business partner, or close personal friend is either named in the proposal or may be invited to participate in the research.
    - A member and the PI actively collaborating in other research or have had a close professional relationship in the past (e.g., past collaborations, advisor-student, etc.).
    - A member and a primary member of the applicant team who have had a longstanding professional disagreement that could be perceived to affect the member's objectivity.

Staff Member Conflicts

CDC's extramural research programs support scientists at universities and other organizations to conduct studies addressing important public health problems in our communities. The success of these extramural research programs is dependent, in part, upon the active involvement of CDC scientists. Through their leadership, CDC ensures that selection of grantees for research funds is unbiased and based upon scientific merit and that high quality research is implemented to help guide public health practice and policy.

CDC staff must avoid real or perceived conflicts of interest in the review and allocation of resources for extramural research. Standards of ethical conduct that address conflicts of interest include guidelines developed for federal staff, university employees, and members of professional societies. CDC employees as well as persons on temporary assignment at CDC (e.g., residents, interns, fellows, IPAs, etc.) are covered by one or more of these guidelines. In addition, persons working at CDC may be required by their CIO to sign and comply with ethical standards for federal employees, regardless of the permanency of their assignment, if they are involved in programmatic or review activities related to funding extramural research.

Conflicts of interest arise if CDC staff participate in the review or allocation of resources when there is a real or perceived possibility of their (1) personal financial gain, (2) partiality towards particular individuals or organizations, or (3) misuse of a government position, title, or authority to further personal or professional interests, including inducement of personal benefits for CDC staff or disclosure of nonpublic information.

1. **Conflicts of financial interest.** Conflicts of interest arise if CDC staff participate in reviews or resource allocation if they, their spouse, minor children, partner or close professional associates have a financial interest, including ownership of stock and employment, in an organization submitting an application for funding, or if they are negotiating to accept employment in an organization submitting an application for funding.

2. **Conflicts of partiality or misuse of government position.** Conflicts arise when CDC staff participate in reviews or resource allocation when they have a close professional, scientific, or personal relationship with the individual applicant or organization. Such relationships might include faculty affiliation, officer, director, member, owner, trustee, expert, advisor, consultant (with or without compensation), employee, family member, or friend.

Conflicts also arise when CDC staff with programmatic interest in specific areas of research contained in a solicitation announcement participate in any aspect of the scientific review of applications responding to that announcement. Programmatic interest can include activities such as setting research policy and program direction, overseeing specific scientific programs, collaborating on a research project submitted in response to the announcement, or recent collaboration, e.g., joint authorship on a manuscript related to the specific topic, with an applicant who is currently submitting an application for review. Also, conflicts arise when CDC staff participate in resource allocation decisions that occur following the scientific review of applications if they plan on collaborating with the applicants or serving as project officers on applications under consideration.

To avoid conflicts of interest: Potential conflicts of interest should be expected occasionally, given the extent of CDC staff involvement in public health activities. CDC staff must notify the person responsible for their assignment (in most cases their supervisor) when they become aware of a potential conflict. Staff may wish to prepare a written memo though this is not required unless requested. Disclosing potential conflicts should be seen as positive and important to the perceived integrity of the individual, program, and agency.

CDC staff may avoid conflicts in the instances described above by recusing themselves, e.g., not participating in review or resource allocation-related activities. Examples of such review activities include selecting members of the review committee, assigning reviewers to specific proposals, serving as the federal official overseeing the review committee, collecting and calculating review scores, writing summary statements, actively participating in proposal reviews or project evaluations, and making funding recommendations.

By developing lines of separation between programmatic and review staff, CDC can reduce the frequency of conflicts of interest. However, if CDC staff wish to participate when there is a possibility of a real or perceived conflict of interest, then an official CDC designee (e.g., the CDC Ethics Officer or the Officer's designee) should determine the level of participation that is warranted. The level of financial or other involvement, the nature of the relationship, and the nature and importance of the employee's role in the matter may be considered in this decision.

For more detailed information the reader is referred to the following documents:

1. Standards of Ethical Conduct for Employees of the Executive Branch, Office of Government Ethics, January 1998
2. Title 18 of the USC Conflict of Interest Statute

3. Summary of Procurement Integrity Rules. Office of the General Counsel, Ethics Division, DHHS, April 1998
4. Handbook for Scientific Review Administrators, NIH, April 1997

Documentation of Conflict of Interest

The CDC staff uses similar criteria for conflict of interest and confidentiality as does the National Institutes of Health. Before applications are mailed to peer review panel or other advisory committee members, a signed statement is obtained from each reviewer certifying that they understand and will abide by the conflict of interest/confidentiality rules. Also, it is the responsibility of the Executive Secretary of each panel to identify conflict of interest cases when preparing member review assignment lists and before mailing applications. Members of peer review and other advisory panels are not to receive either the applications or the reviewer assignments for applications for which a conflict exists. At the panel meetings, members who must recuse themselves sign a form to record their absence.

Confidentiality

All materials pertinent to the applications under review are privileged communications prepared for use only by reviewers and staff, and should not be shown to or discussed with any other individual. Panel members must not solicit opinions or reviews on particular proposals or parts thereof from experts outside the panel. Members may, however, suggest scientists from whom the staff may subsequently obtain advice. At the peer review meetings, panel members are not to discuss proposals with members of other panels and are required to leave all review materials with the staff at the conclusion of the review meeting. Privileged information found in proposals is not to be used for the benefit of the panel member or shared with anyone.

Under no circumstances should panel members advise investigators, their organizations, or anyone else of recommendations or discuss panel meeting proceedings with others. Investigators may be led into unwise actions on the basis of premature or erroneous information. Such advice also represents an unfair intrusion into the privileged nature of the proceedings and invades the privacy of the recommendations of panelists. A breach of confidentiality could deter qualified reviewers from serving on advisory panels and inhibit those who do serve from engaging in free and full discussion of recommendations. Requests for information and telephone inquiries or correspondence from applicant investigators must be directed to the CDC staff for reply.

In terms of the staff, much of the same admonitions apply. In the pre-application stage, the release of any information that would give an applicant an unfair advantage is prohibited. During the peer review process, staff should maintain a blackout of all information about the review process including names of reviewers serving on peer review panels, names of peer reviewers assigned to review specific applications, priority scores etc. Again common sense and good judgement must prevail. Release of information, can invade the privacy of reviewers, can be misleading to applicants, can damage the credibility of the review process and can cause difficulties and embarrassment.

After the review process is complete and letters and summary statements are released, discussions with applicants can be expected. Appropriate discussions may involve matters directly related to the content of the Summary Statement. An alphabetical list of all peer review panel members is made available after the review process is over; the roster is a matter of public record and is available at any time. The list of awardees is listed on the Internet after they have been approved by the Commanding General and notified of their success.

Lobbying

Panel members who are on federal travel status may not participate in any lobbying efforts during the time they are at panel meetings. As government advisors at panel meetings, members should not discuss their own government-funded grants or pending federal proposals with government officials on meeting days. During the same period, panel members also should not lobby members of Congress or their staff on proposed or pending legislation or appropriations.

Scientific Misconduct

DEFINITION: Research misconduct is fabrication, falsification, or plagiarism in proposing, performing, or reviewing research or in reporting research results. A finding of research misconduct requires:

- A significant departure from accepted practices of the scientific community for maintaining the integrity of the research record.
- The misconduct be committed intentionally or knowingly or in reckless disregard of accepted practices.
- The allegation be proven by the preponderance of the evidence.

It does not include honest errors, honest differences in interpretations, or judgments of data. It also does not include unintentional failure to comply with federal requirements affecting specific aspects of the conduct of research, e.g., the protection of human subjects, and the welfare of laboratory animals.

Office of Research Integrity

This office has been established by the Public Health Service (PHS). Grant awards are made only to applicant institutions that have filed an acceptable assurance with the Office of Research Integrity (ORI), PHS. This assurance must indicate that the institution has established policies and an administrative process that meets the regulation requirements for reviewing, investigating, and reporting allegations of misconduct in science in connection with PHS-sponsored research. This office is located in Suite 700, Rockwall Building II, 5515 Security Lane, Rockville, MD 20852 and can be reached at 1-301 443-5377.

ORI Sanction List

An electronic bulletin board is available with information directly provided by ORI containing names of individuals subject to administrative sanctions and pending cases. Access to this information can be obtained via the Internet using the following address: *ori.dhhs.gov*. If an individual has been prohibited from applying for or receiving PHS funds, that person's name will appear on the bulletin board along with information describing the administrative sanctions. The bulletin board is of special interest since it also provides information on persons subject to other types of administrative actions, such as prohibition from serving on PHS committees. Hard copies of these lists are also available and can be obtained by contacting the ORI office directly.

Cases that Come to the Attention of Staff

There may be misconduct allegations that are brought to the attention of staff by letter or during the course of ongoing/annual review of funded grants. In such cases, the staff should in no way act impulsively or disclose such matters to others. Strict confidentiality should be maintained. The proper course of action is to discuss the allegation with the senior Center staff.

Pending Cases

Review of competing proposals will ordinarily not be delayed by concerns about possible misconduct or by a pending or ongoing inquiry or investigation. The Executive Secretary/Program Staff play a pivotal role in handling information about pending cases where an investigator on an application has been charged with scientific misconduct. This matter should not be discussed during the peer or programmatic review of the application, since it may affect the outcome of the review. If the issue is raised by any advisory panel, members should be told the case is under investigation and the allegations should not be considered in the evaluation of the application. However, if the staff perceives that the information is compromising the review, the application should be administratively deferred after consultation with supervisors. Subsequently, the concerns should be forwarded to appropriate CDC staff for a determination of what future action is warranted.

New Allegations

The same procedure should be followed when, during the peer or programmatic review of applications, panel members raise new allegations of possible misconduct. For example, concerns may arise regarding possible plagiarism, ownership of data, or questionable data in support of the research proposed. In all such cases, it is essential that the seriousness of such allegations be stressed to the panel and the potential for harm if confidentiality is not strictly observed. Generally, what appears to be a relatively "minor" impropriety such as the use of small amounts of textbook material, without attribution in a background section of the proposal, should not prevent the peer review panel from providing a fair review.

The general principle is that if the peer or programmatic review panel is able to provide an unbiased review, unaffected by the suspicions of misconduct, it should do so. However, again, if

the staff perceives that the information is compromising the review, the application should be administratively deferred after consultation with supervisors. Subsequently, the concerns should be forwarded to the appropriate CDC staff for a determination of what future action is warranted.

If the review of an application proceeds, it is important that the preparation of the summary statement or correspondence is carefully monitored to ensure that no inappropriate details or comments about the peer or programmatic review panel discussions are expressed in those documents.

The following subjects have been alluded to only briefly in another section of this manual

Research Involving Human Subjects and/or Anatomical Substances

The complete draft CDC manual on research involving human subjects is available at the CDC Web site (http://www.cdc.gov/od/ads/procphrp.pdf). Two sections are included here because of their concise summary of review group and CDC staff office responsibilities.

Responsibilities of Peer Review Groups

The review group is expected to review the human subjects protocol in the application (if applicable). The review will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects, and the importance of the knowledge to be gained.

For applications involving human participants, the review group may recommend:

(a) Approval of the application without any human subjects restrictions.

(b) Approval of the application but with comments made to the applicant regarding human subjects protections.

© Limitations of the work proposed, the imposition of restrictions, the elimination of concerns relating to the protection of human subjects prior to the release of an award.

(d) Disapproval of the application if the research risks are sufficiently serious and protection against the risks is so inadequate as to make the entire application unacceptable.

Preparation of Summary Statements

A section must be provided in the Summary Statement reflecting the review group's evaluation of the use of the human subjects. If there are any restrictions, limitations, concerns and comments relating to the human subjects, they must be addressed in the Summary Statement.

BRIEF SUMMARY OF ROLES AND RESPONSIBILITIES

1. CIO Officials

a. Identify in the Program Announcement whether projects funded could involve humans as subjects.

b. Review application for human subjects designation, appropriateness of exemptions, and adequacy of information provided.

c. Follow up with applicant whenever designation is inappropriate or human subjects-related information is lacking.

d. Brief ORG members regarding review of the human subjects protocol.

e. Prepare Summary Statement with paragraph on human subjects.

f. Resolve concerns with applicants to be funded.

g. Review applications to be funded for human participants designation, and adequacy of information provided. Signs the "Tracking Form for Contracts, Purchase & Task Orders, Modifications to Contracts, and for New, Renewal, and Noncompeting Continuation Grants and Cooperative Agreements" that must be submitted with funding memoranda. Notify GMB of any special restrictions in research procedures.

h. Monitor funded programs for changes in human subjects involvement, and projects without definite plans for human subjects involvement (e.g., training grants).

2. Review Group

a. Reviews human subjects protocol.

b. Reaches agreement on recommendation on human subjects protections.

3. Grants Management Branch

a. Reviews documentation in grant files.

b. Follows up with CIO Officials if discrepancies exist.

c. Documents that assurances and certifications are in place.

d. Requests single project assurances where required.

Research Involving Animals

Definition of Animal

Any live non-human vertebrate.

Alternatives

Applicants are requested to identify:

- The services (computer databases, literature searches, etc.) used to obtain information on alternatives to painful procedures. This includes alleviated pain.

- Identify the databases searched to ensure that unnecessary duplication of previous experiments does not occur.

Rationale/Justification for Using Animals

Applicants are requested to provide a statement of the rationale/justification for using animals. Were alternatives to animal use considered, e.g., computer modeling, cell cultures, etc.? Alternatives to the use of animals must be thoroughly investigated prior to submission of any proposal involving animals.

Species Identification and Rationale/Justification

Applicants are requested to identify the species of animals to be used and the rationale/justification for their use. Why was this particular animal model(s) chosen? Is there a unique quality or usefulness about this species that warrants its selection for use in the proposed research?

Number of Animals Required and Rationale/Justification

Applicants are requested to provide the number of each species of animals to be used by experimental design and a scientific/mathematical rationale/justification for how it was determined to be the minimum number required to obtain valid results.

Experimental Design

Applicants are requested to provide a complete description of the proposed use of the animals by experimental design. This must include surgical procedures, biosamples (frequency, volume, harvest site, and method of tissue collection), and adjuvants and other injections (agent, dosage, route, and anatomical site of administration).

Anesthesia/Analgesia Tranquilization

Applicants are asked to describe what anesthetics, tranquilizers, and analgesics will be used by agent, dosage, route, and anatomical site of administration. If none are to be used, an explanation is requested.

Study Endpoint

Applicants are asked: What is the projected endpoint or termination of the study for the animals?

Euthanasia or Final Disposition

Applicants are requested to describe the method of euthanasia by agent, dosage, route, and anatomical site of administration. If animals are not euthanized, final disposition of the animals must be indicated.

Institutional Animal Care and Use Committee(s) (IACUC) Approval

Evidence must be provided of protocol approval from the IACUC of the institution where animal research will be performed including any subcontracting facility. If it was not possible to have the protocol reviewed by the Committee prior to submission of the proposal, then this should be so stated. Evidence of committee review can follow proposal submission, but must be provided prior to award. Research will not be funded without evidence of approval from the IACUC.
U.S. Department of Agriculture (USDA) Health Inspection Report

Applicants are requested to include a copy of the most recent USDA Inspection Report for the facility(ies) where the animal research will be performed.

Qualifications

Applicants are asked to provide information on the qualifications and training of personnel performing the animal procedures. It must specifically address the training and experience these personnel possess in using and manipulating the species of animals detailed in the proposal.

Accreditation

One of the following must be provided for each facility where the animal research will be conducted:

1. Evidence that the facility is accredited by the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC-I).

2. A copy of the Institutional Letter of Assurance of Compliance with the "Public Health Service Policy on Humane Care and Use of Laboratory Animals," revised September 1986.

A statement signed by the Institutional Official that the care and use of animals will be performed according to the National Research Council 1996 "Guide for the Care and Use of Laboratory Animals" and applicable Federal regulations.

Principal Investigator Signed Assurances

The PI must provide the following signed assurances:

1. I assure that discomfort and injury to animals will be limited to that which is unavoidable in the conduct of scientifically valuable research and that analgesic, anesthetic, and tranquilizing drugs will be used where indicated and appropriate to minimize discomfort and pain to animals.

2. I assure that the animals authorized for use in this protocol will be used only in the activities, manner, and quantities described herein, unless a deviation is specifically approved by my IACUC and the CDC Animal Use policies.

3. I accept full responsibility for the proper care and use of the animals during the conduct of research outlined in the proposal.

4. I verify that I have made a reasonably good faith effort to ensure that this protocol is not an unnecessary duplication of previous experiments.

5. I verify that the personnel performing the animal procedures/manipulations described in this protocol are technically competent in those procedures and have received training on the use of animals in research as required by the Animal Welfare Act of 1985.

6. I assure that I have consulted with an individual who is qualified to evaluate the statistical design or strategy of this proposal and that the minimum number of animals needed for scientific validity will be used.

Biohazards/Safety Program Plan

Each of the applicable items below must be addressed in a proposal appendix entitled "Safety Program Plan" and must be prepared specifically for the proposal. Each section should be operation/research specific and addressed in order. Institutional safety manuals may be referenced; however, it is not necessary to send copies of Facility Safety Plan (FSP) or Standard Operating Procedures (SOPs). A list of program contents with a brief description of each item (maximum 3 pages) is acceptable. If not applicable, this should be stated. Applicants should provide an Internet or Web address, if available, for additional safety and occupational health information. Those items that do not apply to the proposed research should be labeled as "not applicable" or " N/A."

Affirmation of Safety

The PI (recipient) shall submit the following paragraph as affirmation that a safety program is in place and in accordance with all applicable regulations.

> (*Recipient name*) affirms that there is an existing safety program that is an accordance with appropriate federal, state, and local regulations, as required by the Occupational Safety and Health Act; that hazards have been identified, eliminated, and/or controlled; and that research may be performed safely under laboratory conditions. *Recipient name* shall be held responsible and liable for inaccuracies of the information provided failure to implement an effective safety and occupational health program, and/or adverse conditions that may result from the failure of the recipient to identify hazard information.
> *Signature of Recipient, Date*

Research Operations/Standard Operating Procedures (SOPS)

Safety procedures relating to the research operation should include but are not limited to the following: description of safety procedures for performing the protocol:

- Description of any special skills, training, and SOPs to assure safe research operations (Safety Committee, HAZCOM, Blood borne Pathogen, and Chemical Hygiene, etc.).

- Description of medical surveillance and support.

Facility Equipment and Description

This should include a description of any biological safety cabinets, ventilation system employed and personal protective equipment.
Hazard Analysis

Applicants are requested to include a description of each hazard identified, hazard analysis based on maximum credible event, and plan to minimize or eliminate hazards (infection, toxic substance, and biological hazards).

Radioactive Materials

If radioactive materials are used, the materials and the disposal method should be identified. A copy of the Nuclear Regulatory Committee (NRC)-approved license or agreement must be submitted. If no such material is to be used, it should be so stated.

Recombinant DNA

Research involving recombinant DNA must meet or exceed NIH Guidelines for Research Involving Recombinant DNA Molecules, January 1997 edition. Applicants must include a written approval letter from the organization's Institutional Biosafety Committee (IBC). The IBC reviews all applications to perform protocols involving recombinant DNA (biohazardous material). If not applicable, it should be so stated.

Copies of the above NIH Guidelines are available at:

Fax:	(301) 496-9839
Phone:	(301) 496-9838
E-mail:	www.nih.gov/od/orda
Mail:	Office of Recombinant DNA Activities National Institutes of Health, MSC 7010 6000 Executive Boulevard, Suite 302 Bethesda, MD 20892-7010

APPENDIX I
Program Announcement Templates

APPENDIX CONTENT

AI-1 Program Announcement - Summary Outline

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[or Agency for Toxic Substances and Disease Registry]

Notice of Availability of Funds

[program title]

A. Purpose
B. Eligible Applicants

    Maximum Competition
    Limited Competition
    Single Source

C. Availability of Funds

    Direct Assistance
    Use of Funds
    Recipient Financial Participation
    Funding Priority
    Funding Preferences

D. Program Requirements

E. Application Content

F. Submission and Deadline

G. Evaluation Criteria

H. Other Requirements

I. Authority and Catalog of Federal Domestic Assistance Number

J. Where to Obtain Additional Information

Billing Code: 4163-18-P [Billing Code for CDC except NIOSH]
Billing Code: 4163-19-P [Billing Code for NIOSH]
Billing Code: 4163-70-P [Billing Code for ATSDR]

AI-2 Program Announcement - Annotated Outline

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Centers for Disease Control and Prevention
[or Agency for Toxic Substances and Disease Registry]
Notice of Availability of Funds

[insert program title]

A. Purpose

Begin with the following:

The Centers for Disease Control and Prevention (CDC) [or the Agency for Toxic Substances and Disease Registry (ATSDR)] announces the availability of fiscal year (FY) [**insert year**] funds for a cooperative agreement [**or grant**] program for [**insert name of program**]. This program addresses the "Healthy People 2000" priority area(s) [**insert one or more categories from the following list**].

1. Physical Activity and Fitness
2. Nutrition
3. Tobacco
4. Substance Abuse: Alcohol and Other Drugs
5. Family Planning
6. Mental Health and Mental Disorders
7. Violent and Abusive Behavior
8. Educational and Community-Based Programs
9. Unintentional Injuries
10. Occupational Safety and Health
11. Environmental Health
12. Food and Drug Safety
13. Oral Health
14. Maternal and Infant Health
15. Heart Disease and Stroke

16. Cancer
17. Diabetes and Chronic Disabling Conditions
18. HIV Infection
Sexually Transmitted Diseases
Immunization and Infectious Diseases
Clinical Preventive Services
Surveillance and Data Systems

Describe why assistance funds are being made available.

The purpose of the program is to [**complete**].

B. Eligible Applicants

Authorizing legislation and program regulations specify eligibility for grant and cooperative agreement programs. In general, assistance is provided to educational institutions, nonprofit organizations and institutions, and governments and their agencies. For-profit organizations are eligible to receive awards under all financial assistance programs unless legislation prohibits such an award. If for-profit organizations are eligible, the applications must be reviewed by a special emphasis panel (SEP) or a chartered study section.

Specify the types of organizations that are eligible to compete. It is federal policy to solicit applications for financial assistance from all eligible organizations. Awards will be made only after maximum competition.

Maximum Competition

Use the following language to ensure that applications are solicited from a wide range of non-profit organizations. If for-profit organizations are also eligible, add bracketed phrases.

Applications may be submitted by public and private nonprofit [and for-profit] organizations and by governments and their agencies; that is, universities, colleges, research institutions, hospitals, other public and private nonprofit [and for-profit] organizations, state and local governments or their bona fide agents, and federally recognized Indian tribal governments, Indian tribes, or Indian tribal organizations.

Limited Competition

Competition may be limited by any of the following:

- Legislation.
- An unusual and compelling urgency (e.g., responding to crisis conditions after a hurricane) does not allow enough time to publish a program announcement for maximum competition, even under “time constraint” procedures.
- Program expansion may be undertaken only by current recipients (i.e., applications will be supplemental).

- Published program priorities restrict competition.
- Only a specific group of organizations (e.g., state health departments) can perform the project activities.

For example, if competition is limited to state health departments, begin the Eligible Applicant section with the following.

Assistance will be provided only to the health departments of states or their bona fide agents, including the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, the Commonwealth of the Northern Mariana Islands, American Samoa, Guam, federally recognized Indian tribal governments, the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. In consultation with states, assistance may be provided to political subdivisions of states.

After this paragraph, explain why competition is limited to state health departments.

Single Source

A single source may be considered for an award only when:

- Evidence is compelling that one organization has superior qualifications; that is, no other sources could fulfill the objective of the program
- There is an urgency to get the project under way, such as providing health services in response to a crisis that endangers public health
- A single source is mandated by the agency's appropriation or congressional report language

Begin the Eligible Applicants Section in a single source announcement with the following:

> **Assistance will be provided only to [insert identification of source]. No other applications are solicited.**

After this introductory paragraph, explain why competition is being limited to a single source.

Use the following text as the last paragraph for this section:

> NOTE: Public Law 104-65 states that an organization described in section 501(c)(4) of the Internal Revenue Code of 1986 that engages in lobbying activities is not eligible to receive Federal funds constituting an award, grant, cooperative agreement, contract, loan or any other form.

C. Availability of Funds

State the amount of available funds for the given fiscal year as well as any funds that are anticipated for future years. If funds are not yet available but are anticipated before the award, explain. State the number of anticipated awards as well as the range and the average dollar amount.

State the budget period and the project period for which the project will be funded. A project period may consist of one or more budget periods but may not exceed 5 years. A budget period is usually 12 months.

Use the following text for this section:

> Approximately $_____ is available in FY [insert year] to fund approximately ____ awards. It is expected that the average award will be $_____, ranging from $____ to $_____. It is expected that the awards will begin on or about _____ and will be made for a 12-month budget period within a project period of up to _____ years. Funding estimates may change.
>
> Continuation awards within an approved project period will be made on the basis of satisfactory progress as evidenced by required reports and the availability of funds.

Direct Assistance

If direct assistance (DA) is authorized by legislation and available under a program, use the following statement:

> You may request Federal personnel, equipment, or supplies as direct assistance, in lieu of a portion of financial assistance.

Use of Funds

Use this section to describe limitations (if any) on the use of cooperative agreement or grant funds. For example, if a program has a limit on administrative costs, or a prohibition on the purchase of equipment, address the requirement here.

Recipient Financial Participation

Include this section when financial participation is required. If recipient financial participation is required by legislative authority, use the following:

> Recipient financial participation is required for this program in accordance with the authorizing legislation.

Complete this paragraph by citing the specific requirements of the authority.

The following is an example from the Breast and Cervical Cancer Screening announcement:

> *Section 1502(a) and (b)(1), (2), and (3) states that matching funds are required from non-federal sources in an amount not less than $1 for each $3 of federal funds awarded under this program.*

The matching funds may be in cash or its equivalent in-kind or donated services, including equipment, fairly evaluated. The contributions may be made directly or through donations from public or private entities.

In some states/territories, non-federal funds from a variety of sources may presently be used to support one or more of the breast and cervical cancer early detection activities described in this program announcement.

Programs may also choose to require a match. The following example is from an STD prevention announcement:

Awards for these optional activities will be made on a competitive basis for as much as $200,000 per year in 2:1 matching funds (i.e., $2 awarded for each $1 of new public or private resources). Therefore, as much as $300,000 in combined federal ($200,000), state or local ($100,000) funding will be available annually for enhanced STD activities for each project area.

Funds from a variety of non-federal sources may be used to support one or more existing core capacity activities. Non-federal funds in excess of the average amount expended during the 2 years preceding the first fiscal year that a state applies for funding may be used as match. You may not supplant existing program efforts through other federal or non-federal sources.

Funding Priority

Funding priority means that the awarding agency intends to give priority to one or more particular kinds of projects. Describe the funding priority so that applicants will understand why funds may be limited to particular kinds of projects, and describe how the funding priority will be applied in deciding which applications to fund.

OMB Circular A-102 requires agencies to provide the public with an opportunity to comment on intended funding priorities. Adequate time, usually 30 days from publication of the announcement in the Federal Register, should be given for public comment.

The last paragraph of this section should read as follows:

Interested persons are invited to comment on the proposed funding priority. All comments received within 30 days after publication in the Federal Register will be considered before the final funding priority is established. If the funding priority changes because of comments received, a revised announcement will be published in the Federal Register, and revised applications will be accepted before the final selections are made. Address comments to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

If time does not permit comments, the following should be the last paragraph:

> Public comments are not being solicited because time is insufficient for solicitation and review of comments before the funding date.

Funding Preferences

Funding preferences may be given to, for example, a type or category of application, such as applications from current recipients, applications from new recipients, or applications from specific locations (to achieve geographic distribution).

D. Program Requirements

For grants, describe the program areas of interest and support, and list the requirements for the program recipients.

For cooperative agreements, describe the collaborative activities of the recipient and CDC. Department of Health and Human Services policy requires an explicit statement of CDC program staff's involvement, which is expected to be substantial. Set forth intentions clearly, for example: pooling of data, joint recipient-program staff participation in particular decisions, or possible recipient-program staff cooperation in preparing and publishing results. Begin this description with the following statement:

> In conducting activities to achieve the purpose of this program, the recipient will be responsible for the activities under 1. (Recipient Activities), and CDC will be responsible for the activities listed under 2. (CDC Activities).

If the research project will have CDC scientists as co-investigators, insert the following under the CDC Activities section:

> Assist in the development of a research protocol for IRB review by all cooperating institutions participating in the research project.
>
> The CDC IRB will review and approve the protocol initially and on at least an annual basis until the research project is completed.

E. Application Content

Letter of Intent (LOI)

If an announcement will use a letter of intent (LOI) submission, indicate the information potential applicants must provide.

Applications

Whenever possible, use the following language to simplify the program announcement and to ensure that the applicants address the recipient activities in light of the evaluation criteria.

Use the information in the Program Requirements, Other Requirements, and Evaluation Criteria sections to develop the application content. Your application will be evaluated on the criteria listed, so it is important to follow them in laying out your program plan. The narrative should be no more than [insert number] double-spaced pages, printed on one side, with one inch margins, and unreduced font.

Direct Assistance

To request a Federal assignee for new position, the applicant must provide sufficient information for program and Human Resources Management Office (HRMO) to develop and grade a position description.

To request new direct-assistance assignees, include:

Number of assignees requested
Description of the position and proposed duties
Ability or inability to hire locally with financial assistance
4. Justification for request
Organizational chart and name of intended supervisor
Opportunities for training, education, and work experiences for assignees
Description of assignee's access to computer equipment for communication with CDC (e.g., personal computer at home, personal computer at workstation, shared computer at workstation on site, shared computer at a central office)

F. Submission and Deadline

Letter of Intent

If an LOI is requested, provide the due date. Also indicate whether the LOI is required or optional, whether it will be used to eliminate potential applicants or to enable CDC to determine level of interest in the announcement, or whether the LOI will be used for other reasons.

Describe the information potential applicants must submit and then include the following:

Your letter of intent should include the following information.

On or before [xxxxxxx], 200[ ], submit the letter of intent to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Application

Use the following language:

Submit the [choose one: original and two copies of PHS 5161-1 (OMB Number 0937-0189) OR original and two copies of CDC 0.1246 OR the original and five copies of PHS-398 (OMB Number 0925-0001) (adhere to the instructions on the Errata Instruction Sheet for PHS 398)]. Forms are in the application kit.

On or before [xxxxxxx], 200[ ], submit the application to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

Deadline

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date.

2. Sent on or before the deadline date and received in time for orderly processing. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

Late Applications: Applications that do not meet the criteria in (1) or (2) above are considered late applications, will not be considered, and will be returned to the applicant.

One of the following application forms may be used:

PHS FORM 398 The PHS 398 form is used for applications for Public Health Service (PHS) research grants. The PHS 398 is required for all new, revised, competing continuation, and supplemental research grant and cooperative agreement applications.

PHS FORM 5161-1 The PHS 5161-1 is used for a variety of programs for all new, revised, competing continuation, non-competing continuation, and supplemental applications. The basic form (Standard Form 424) is prescribed by OMB Circular A-102 for use by state and local government applicants. The form is also intended for use by non-governmental applicants seeking support for health services projects.

CDC FORM 0.1246 The CDC 0.1246(E), which has been approved by DHHS for state and specified local governments applying to programs that are available only to state and local governments, is for all new, revised, competing continuation, non-competing continuation, and supplemental applications.

All the above forms are available for downloading from the CDC Funding homepage by applicant organizations.

G. Evaluation Criteria

Letter of Intent

If LOIs are requested **AND** if they will be evaluated to eliminate potential applicants, you must specify the criteria to be used and the process you will use to notify successful and unsuccessful applicants.

Application

Begin the Evaluation Criteria section with the following:

> Each application will be evaluated individually against the following criteria by an independent review group appointed by CDC [ATSDR].

List the criteria to be used in evaluating the applications. Give the weights applicable to the criteria, even if all weights are equal. The following criteria are the minimum.

> Significance
> Approach
> Innovation
> Investigators
> Environment
> Budget (Reviewed, but not scored)

If human subjects protections is or may be required, the following criterion must also be included:

> Does the application adequately address the requirements of 45 CFR 46 for the protection of human subjects? (Not scored.)

Research projects also require the following criteria, which should be included in another scored criterion:

> The degree to which the applicant has met the CDC Policy requirements regarding the inclusion of women, ethnic, and racial groups in the proposed research. This includes:

1. The proposed plan for the inclusion of both sexes and racial and ethnic minority populations for appropriate representation.
2. The proposed justification when representation is limited or absent.
3. A statement as to whether the design of the study is adequate to measure differences when warranted.
4. A statement as to whether the plans for recruitment and outreach for study participants include the process of establishing partnerships with community(ies) and recognition of mutual benefits.

Other Requirements

Technical Reporting Requirements

Use the following language:

Provide CDC with the original plus two copies of**:**

1. Progress reports (annual, semiannual, or quarterly).
2. Financial status report, no more than 90 days after the end of the budget period.
3. Final financial report and performance report, no more than 90 days after the end of the project period.

Send all reports to the Grants Management Specialist identified in the "Where to Obtain Additional Information" section of this announcement.

All other requirements will be referenced by the title and number in the announcement, but the descriptions of the requirements will be included in the application kit. In the announcement, list only those requirements that are applicable. For explanations of the requirements, see the document entitled "Descriptions of Other Requirements" in the GMB homepage under Program Announcements:

http://inside.cdc.gov/intranet/pgo/othereq.htm

I. Authority and Catalog of Federal Domestic Assistance Number

Use the following:

This program is authorized under section _____ of the Public Health Service Act, 42 U.S.C. section _____, as amended. The Catalog of Federal Domestic Assistance number is _____.

Note: You must use parallel construction. If a section and subsection from the PHS Act are cited, cite the section and subsection of the United States Code (U.S.C.). If only a section of the PHS Act is cited, do not cite the U.S.C. subsections, for example, 301, but 301a in 42 U.S.C. 241(a). A list of CDC and ATSDR authorizing legislation is available on the CDC intranet.

List of Catalog of Federal Domestic Assistance Numbers

93.116* Project Grants and Cooperative Agreements for Tuberculosis Control Programs
93.118 Acquired Immunodeficiency Syndrome (AIDS) Activity
93.135 Centers for Research and Demonstration for Health Promotion and Disease Prevention (Prevention Centers)
93.136 Injury Prevention and Control Research and State Grant Projects
93.161* Health Program for Toxic Substances and Disease Registry
93.184* Disabilities Prevention
93.185* Immunization Research, Demonstration, Public Information, and Education - Education, Training, and Clinical Skills Improvement Projects
93.197* Childhood Lead Poisoning Prevention Projects - State and Community-Based Childhood Lead Poisoning Prevention Program
93.200* Educating Health Professionals Regarding Environmentally Hazardous Substances
93.201* Public Health Assessment and Related Site-Specific Biological Testing
93.203* Health Activities Recommendation Panel Health Activities
93.204* Surveillance of Hazardous Substance Emergency Events
93.205* Health Outcome Studies to Hazardous Substances and Adverse Health Effects
93.206* Health Studies Initiative of Priority Health Conditions
93.207* Surveillance of the Relationship Between Hazardous Substances Exposure and Adverse Health Outcomes
93.208 Great Lakes Human Health Effects Research
93.262 Occupational Safety and Health Research Grants
93.263 Occupational Safety and Health - Training Grants
93.268* Childhood Immunization Grants
93.283* Centers for Disease Control and Prevention - Investigations and Technical Assistance
93.919* Cooperative Agreements for State-Based Comprehensive Breast and Cervical Cancer Early Detection Programs
93.938* Cooperative Agreements to Support Comprehensive School Health Programs to Prevent the Spread of HIV and Other Important Health Problems (SHEPSA)
93.939* HIV Prevention Activities - Non-governmental Organization
93.940* HIV Prevention Activities - Health Department Based
93.941* HIV Demonstration, Research, Public and Professional Education Projects
93.942 Research, Treatment, and Education Programs of Lyme Disease in the United States
93.943 Epidemiologic Research Studies of Acquired Immunodeficiency Syndrome (AIDS) and Human Immunodeficiency Virus (HIV) Infection in Selected Population Groups
93.944* HIV/AIDS (Human Immunodeficiency Virus and Acquired Immunodeficiency Syndrome) Surveillance
93.945* Assistance Programs for Chronic Disease Prevention and Control
93.946* Cooperative Agreements to Support State-Based Infant Health Initiative Programs
93.947* Tuberculosis - Demonstration, Research, Public and Professional Education Projects

93.955* Health and Safety Programs for Construction Work and Model Construction Safety and Health
93.956* Centers for Agricultural Research, Education, and Disease and Injury Prevention and Occupational Respiratory Disease Musculoskeletal Disorders Evaluation and Rehabilitation
93.957* Occupational Health and Surveillance
93.977* Preventive Health Services - Sexually Transmitted Diseases Control Grants
93.978 Preventive Health Services - Sexually Transmitted Diseases Research, Demonstration, and Public Information and Education Grants
93.988* Cooperative Agreements for State-Based Diabetes Control Programs and Evaluation of Surveillance Systems
93.991 Preventive Health and Health Services Block Grant

* These programs require E.O. 12372 review.

J. Where to Obtain Additional Information

Use the following for all program announcements, except those for sole source and limited competition programs:

To receive additional written information and to request an application kit, call 1-888-GRANTS4 (1-888 472-6874). You will be asked to leave you name and address and will be instructed to identify the Announcement number of interest.

If you have questions after reviewing the contents of all the documents, business management technical assistance may be obtained from:

_____, Grants Management Specialist
Grants Management Branch, Procurement and Grants Office
Centers for Disease Control and Prevention
Room 3000, 2920 Brandywine Road
Atlanta, GA 30341-4146
Telephone number [**insert the number for the Grants Management Specialist**]
E-mail address [**insert address for the Grants Management Specialist**]

For program technical assistance, contact:

Provide the following contact information for the program person who is responsible for providing technical assistance:

Name
Address
Telephone number
E-mail address

This and other CDC [ATSDR] announcements can be found on the CDC home page Internet address - http://www.cdc.gov

For single source and limited competition program announcements, use the following:

To obtain additional information, contact:

_____, Grants Management Specialist
Grants Management Branch, Procurement and Grants Office
Centers for Disease Control and Prevention
Room 3000, 2920 Brandywine Road
Atlanta, GA 30341-4146
Telephone number [**insert number for the Grants Management Specialist**]
E-mail address [**insert address for the Grants Management Specialist**]

This and other CDC [ATSDR] announcements can be found on the CDC home page Internet address - http://www.cdc.gov

For program technical assistance, contact:

Provide the following contact information for the program person who is responsible for providing technical assistance:

Name
Address
Telephone number
E-mail address

All CDC announcements, other than those for NIOSH, will be signed by the Director of Procurement and Grants. Use the following signature:

Dated:

_____

John L. Williams
Director, Procurement and Grants Office

All NIOSH announcements will have the following signature:

Dated:

_____

[insert name of Director]
Director, National Institute for Occupational Safety and Health
Centers for Disease Control and Prevention (CDC)

All ATSDR announcements will have the following signature:

Dated:

_____
[insert name of Deputy Administrator]
Deputy Administrator
Agency for Toxic Substances and Disease Registry

APPENDIX II
Orientation Material

APPENDIX CONTENT

Reviewer's Guide to the Special Emphasis Panel Process

The function of the Special Emphasis Panel (SEP) is to impartially evaluate the merit of applications based on criteria published in the Federal Register announcement. The SEP serves to make recommendations to the CIO Director regarding the quality of each application against published criteria.

As an appointee to the SEP, you will receive the following documents:

- An appointing memo (or letter) from the designated federal official
- Conflict of Interest and Confidentiality Certification
- A copy of the program announcement
- Copies of the applications assigned to you for review
- A copy of the Reviewer's Guide to the SEP Process (this document)
- An agenda for the panel review meeting
- Peer Review Forms (these will also be sent on a diskette or via e-mail for electronic entry)

The first step in the actual review is to familiarize yourself with the program announcement. The announcement will describe the program and list the evaluation criteria you must use when reviewing your applications. These criteria are the ones published in the Federal Register and the ones on the review forms you will complete.

Read the applications you were assigned, keeping in mind the evaluation criteria. Complete a review form for each application, being careful to score the application only against criteria published in the Federal Register. Be careful not to compare any application with another; compare each application with the published criteria only. Comment on strengths and weaknesses of each criterion, and if you have general comments, note them under the "Other Relevant Comments" or "Recommendations" section on the review form. Also note whether the applicant has addressed any "Other Requirements" (e.g., Human Subjects, Paperwork Reduction, etc.) that may be included in the announcement.

NOTE: Please be sure to document strengths and weaknesses for each criterion. The comments you make will not only be used in making decisions regarding which applications will be funded, but also in defending those decisions in case of protests from unfunded applicants. Weaknesses are especially important. Unless you score a criterion at the highest level ("Outstanding"), you should make note of weaknesses to explain why that criterion did not receive an "Outstanding" score.

Additionally, your comments will be incorporated into the Summary Statement for that application. (The Summary Statement outlines the strengths, weaknesses and recommendations noted by the review panel, is returned to the applicant as feedback to the application, and is held in their official grant file for reference, e.g., to be used for Freedom of Information Act inquiries, Congressional inquiries, and so forth). Detailed comments from you will assist the applicant in improving subsequent applications.

Prior to the review meeting, you will be asked to rate applications as being competitive or non-competitive as part of a streamlined (triage) peer review process. You will be sent a triage form to complete prior to the meeting indicating whether you believe each application assigned to you warrants full panel discussion and consideration for funding based on its merit (competitive) or whether it does not (non-competitive). The Executive Secretary will prepare a compilation of this information received from each assigned reviewer of each application. At the beginning of the review meeting, the Chair will ask the panel to very briefly review the status of each application; approximately one-half will be identified as non-competitive and receive no further panel review. The competitive applications will receive a complete and thorough panel review. A final point to note about the streamlined review process is that any panel member can request that an application be fully discussed and the request will be honored.

At the panel review meeting, you will be asked to sign an additional Conflict of Interest form, affirming that you have no vested interest in any applicant organization. If you have a conflict with an applicant, you must leave the room during the discussion of that application; other reviewers must not discuss the application with you.

If you are a primary reviewer, you will present a 10-minute oral summary of your review of the application. This summary will include a BRIEF overview of the application, strengths and weaknesses you noted for each criterion, and your qualitative score (outstanding, excellent, very good, good, acceptable) for each criterion. Your qualitative scores will assist the panel in assigning quantitative scores. If you are the secondary reviewer, you will be asked by the Chairperson to give a 5-minute oral presentation of your review. If you are a reader (third reviewer), you will be asked for oral comments if they differ from, or add substantially to, that of the primary or secondary reviewer.

After presentations by the assigned reviewers, discussion among the panel members will take place. The Chairperson will then ask the panel members for a motion.

The possible motions are:
Recommended for further consideration:

> The application is of sufficient technical and scientific merit to be worthy of support based on the review criteria. All voting members must score the application. The SEP may identify specific concerns or make specific recommendations which will be noted within the summary statement provided to the applicant. These concerns and/or recommendations will be discussed with the applicant if budget discussions and post award administration of the grant/ cooperative agreement takes place.

Not Recommended for Further Consideration:

The application is non-responsive to the published criteria or otherwise deficient in its scientific, technical, managerial, or other relevant aspects. This recommendation may also be made when hazardous or unethical procedures are involved. An application this recommendation is not scored. The specific reasons for the recommendation should be included on the reviewer's evaluation form.

Deferral:

The SEP cannot make a recommendation without additional information or clarification of specific aspects of the application. The Designated Federal Official, in collaboration with the Grants Management Officer, takes the necessary action to obtain the information. The application must be reconsidered prior to the adjournment of the SEP meeting or a special review must be held to reconsider the application.

Non-unanimous recommendations:

If two or more members disagree with the recommendations of the SEP, the dissenting members must prepare a written minority report. The minority report will be incorporated into the "strengths/weaknesses" section of the summary statement. A single dissenting member may prepare a minority report if the member wishes to do so. The minority report should include the opinions of all dissenting members.

After a motion has been made, there will be a discussion of the motion. The Chairperson will then ask for a show of hands of those in favor and those opposed. Once a motion has carried, there will be a discussion of the budget and the duration of support. The budget discussion is important because it will materially assist the program and grants management staff in negotiating an appropriate award. After all aspects of the application discussion has been completed, SEP members will be asked to assign numerical priority scores to the applications. All reviewers then submit their scoring sheets to the Chairperson.

SCORING

The priority score has strong influence on the final funding decision. Therefore, scores should be assigned on the basis of careful and objective consideration of review criteria. Applications should be judged independently of one another, and according to each reviewer's standards of quality. The priority score should not be based on a comparison of one application with another.

- Individual Scores: For each application recommended for further consideration by a panel majority, each reviewer individually and privately records a numerical rating reflecting his/her own opinion of the overall merit of the proposal.

- The Rating Scale: The numerical rating is based on a scale from 1.0 (the most meritorious), to 5.0 (the least meritorious), with increments of 0.1. The approximate numerical equivalents of adjectival ratings are:

Outstanding	1.0 to 1.4
Excellent	1.5 to 1.9
Very Good	2.0 to 2.4
Good	2.5 to 2.9
Acceptable	3.0 to 5.0

Applications **not** recommended for further consideration: When a majority of panelists do not vote to recommend an application, no priority score is required.

- Minority Vote: An individual reviewer voting in the minority to not recommend an application must assign a priority score that can be 5.0 or any appropriate score.

- Overall Panel Priority Score: The scores assigned by each panelist to an application are added, divided by the number voting and multiplied by 100 to provide a three-digit rating representing the final priority score. This priority score is included on the summary statement which is forwarded to the next level of review and then sent to the principal investigator after completion of the review process.

The review of applications is confidential; reviews must not be discussed outside the panel meeting.

If you have any questions about the review process, please contact (DFO)

Name_____ at (Phone. #_____

Chairperson's Script for Special Emphasis Panels

1. **Declare the Special Emphasis Panel (SEP) in Session**:

Invite self-introductions from panel members and staff.

2. **Review Purpose and Role of the SEP**:

The role of the SEP is to perform the peer review of cooperative agreement or grant applications. The term peer review, as used for this meeting, means a thorough examination of applications to provide advice to awarding officials based on an evaluation of the scientific or technical merit of applications. The SEP accomplishes this by reviewing applications and voting to recommend or not to recommend based on the published review criteria.

Comments on the budget are welcomed but should not be considered in arriving at a decision to recommend or not to recommend the application. However, in the case of recommended applications budget recommendations are extremely useful in guiding the program and grant management staff in negotiating the duration and amounts to be awarded.

The Executive Secretary has already explained many of the administrative details to you including the streamlined or triage procedures. Also, you have received a good deal of information prior to the meeting about the administrative and policy considerations associated with such grant reviews. Therefore, I will not repeat them all but highlight a few that I feel are worth mentioning again in order to ensure the proceedings move along smoothly.

3. **Conflict of Interest**:

Introduce Grants Management Specialist who will reaffirm that no member has a conflict of interest (or that individual members will abstain from discussion and voting on any application where a conflict might exist).

Examples of conflicts (more complete information has been previously sent to each panel member:

- A member who is affiliated or has a financial interest in the applicant organization;
- A member who provided assistance to the applicant in the development of the application;
- A member who is a close professional associate, scientific adversary, scientific competitor, former student or mentor or who feels unable to render an objective judgement.

4. **Determine if members have received relevant materials**

5. **Operating Review Procedures**:

You were requested to bring an original and two copies of your reviews of an application assigned to you. If you did not bring the extra copies, please let me know so we can have copies made. These copies will assist the recorder and me in preparing the summary of today's discussions.

For each application, I will ask the primary reviewer to give us an oral summary of what the applicant proposes to do and to discuss his/her assessment of the merits of the application against each individual criterion. We have allotted approximately 10 minutes for this. Following the primary reviewer's presentation, I will ask the secondary reviewer to give a 5-minute oral presentation of his/her review and then the reader (third reviewer) to provide oral comments to address any issues that differ from the primary or secondary reviewer or any additional information wishing to be shared. Each reviewer should start their comments by briefly indicating their overall level of enthusiasm for the application. Following these presentations (and those of any other assignees), panel members will have an opportunity to discuss the application and to ask questions of the primary or secondary reviewer, or reader. (I remind everyone to restrict their comments to those issues addressed in the application). Program and grants management staff are available to assist should any non-scientific grant-related issues arise. Following discussion, I will call for a motion and a second. I will then restate the motion and ask for a discussion. I will then call for a vote. I will vote on all applications. If an application is recommended for further consideration, I will then ask for a discussion of the budget and the duration of support. After budget discussions, I will ask the primary and secondary reviewers and reader to share again their qualitative rating based on the evaluation criteria. The other voting panel members may use these adjectival scores as a guide in arriving at their numeric score for each application. I will then ask that all panel members sign and date their scoring sheets and submit them. If two or more panel members vote in the minority, you must prepare a minority report stating the reasons for differing with the majority opinion. You may submit a consolidated minority report or you may each submit individual reports.

APPENDIX III
Miscellaneous Policy Requirements

APPENDIX CONTENT

AR-1: Human Subjects Requirements

If the proposed project involves research on human participants, the applicant must comply with the Department of Health and Human Services Regulations (45 CFR 46) regarding the protection of human research participants. (see http://www.cdc.gov/od/ads/procphrp.pdf) Assurance must be provided to demonstrate that the project will be subject to initial and continuing reviews by an appropriate institutional review board. The applicant will be responsible for providing evidence of this assurance in accordance with the appropriate guidelines and forms provided in the application kit.

In addition to other applicable committees, Indian Health Service (IHS) institutional review committees also must review the project if any component of IHS will be involved with or will support the research. If any American Indian community is involved, its tribal government must also approve that portion of the project applicable to it.

Unless the awardee holds a Multiple Project Assurance, a Single Project Assurance is required, as well as an assurance for each subcontractor or cooperating institution that has immediate responsibility for human participants.

The Office for Protection from Research Risks (OPRR) at the Department of Health and Human Services (DHHS) negotiates assurances for all activities involving human participants that are supported by the Department of Health and Human Services.

Before a grant or a cooperative agreement can be awarded, an institutional committee must certify a review (described in Part 107 of the PHS Grants Administration Manual and in 45 CFR Part 46). Continuing review is also required.

Note: Whenever a CDC employee is involved in research in which humans are used as subjects and the research is conducted under a grant or a cooperative agreement, Federal liability is possible. Consult the Associate Director for Science for your CIO to ensure the protection of the government's interests. Program staff are to obtain protocol approval through the CDC Human Subjects Manager (use CDC forms 0.1250-1255 as appropriate).

AR-2: Requirements for Inclusion of Women and Racial and Ethnic Minorities in Research

It is the policy of the Centers for Disease Control and Prevention (CDC) and the Agency for Toxic Substances and Disease Registry (ATSDR) to ensure that individuals of both sexes and the various racial and ethnic groups will be included in CDC/ATSDR-supported research projects involving human subjects, whenever feasible and appropriate. Racial and ethnic groups are those defined in OMB Directive No. 15 and include American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander. Applicants shall ensure that women, racial and ethnic minority populations are appropriately represented in applications for research involving human subjects. Where clear and compelling rationale exist that inclusion is inappropriate or not feasible, this situation must be explained as part of the application. This policy does not apply to research studies when the investigator cannot control the race, ethnicity, and/or sex of subjects. Further guidance to this policy is contained in the Federal Register, Vol. 60, No. 179, pages 47947-47951, and dated Friday, September 15, 1995.

AR-3: Animal Subjects Requirements

If the proposed project involves research on animal subjects, compliance with the "PHS Policy on Humane Care and Use of Laboratory Animals by Awardee Institutions" is required. An applicant (as well as each subcontractor or cooperating institution that has immediate responsibility for animal subjects) proposing to use vertebrate animals in CDC-supported activities must file (or have on file) the Animal Welfare Assurance with the Office for the Protection from Research Risks (OPRR) at the National Institutes of Health. The applicant must provide in the application the assurance of compliance number and evidence of review and approval (including the date of the most recent approval) by the Institutional Care and Use Committee (IACUC) .

AR-4: HIV/AIDS Confidentiality Provisions

Recipients must have confidentiality and security provisions to protect data collected through HIV/AIDS surveillance, including copies of local data release policies; employee training in confidentiality provisions; State laws, rules, or regulations pertaining to the protection or release of surveillance information; and physical security of hard copies and electronic files containing confidential surveillance information.

Describe laws, rules, regulations, or health department policies that require or permit the release of patient-identifying information collected under the HIV/AIDS surveillance system to entities outside the public health department; describe also the measures the health department has taken to ensure that persons reported to the surveillance system are protected from further or unlawful disclosure.

Some projects may require Institutional Review Board (IRB) approval or a certificate of confidentiality.

AR-5: HIV Program Review Panel Requirements

Compliance with *Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions* (June 1992) (a copy is in the application kit) is required.

To meet the requirements for a program review panel, you are encouraged to use an existing program review panel, such as the one created by the State health department's HIV/AIDS prevention program. If you form your own program review panel, at least one member must be an employee (or a designated representative) of a State or local health department. List the names of the review panel members on the Assurance of Compliance form, CDC 0.1113, which is also included in the application kit. Submit the program review panel's report that all materials have been approved.
If the proposed project involves hosting a conference, submit the program review panel's report stating that all materials, including the proposed conference agenda, have been approved. Submit a copy of the proposed agenda with the application.

Before funds are used to develop educational materials, determine whether suitable materials already exist in the CDC National AIDS Clearinghouse.

AR-6: Patient Care

Ensure that all STD- or HIV-infected patients enrolled in the proposed project will be linked to an appropriate local care system that can address their specific needs, such as medical care, counseling, social services, and therapy.

AR-7: Executive Order 12372 Review

Applications are subject to Intergovernmental Review of Federal Programs, as governed by Executive Order (E.O.) 12372. The order sets up a system for State and local governmental review of proposed Federal assistance applications. Applicants should contact their State single point of contact (SPOC) as early as possible to alert the SPOC to prospective applications and to receive instructions on the State process. For proposed projects serving more than one State, the applicant is advised to contact the SPOC for each State affected. (The application kit contains a current list of SPOCs.) SPOCs who have recommendations about the State process for applications submitted to CDC should send them, in a document bearing the program announcement number, no more than 60 days after the application deadline date, to:

[ ], Grants Management Specialist
Grants Management Branch, Procurement and Grants Office
Announcement Number [ ]
Centers for Disease Control and Prevention (CDC)
2920 Brandywine Road, Room 3000
Atlanta, Georgia 30341-4146

Indian tribes must request tribal government review of their applications.

If Indian tribes are eligible for the program, change the sentence about SPOC recommendations as follows:

SPOCs or tribal governments that have recommendations about an application submitted to CDC should send them, in a document bearing the program announcement number, no more than 60 days after the application deadline date, to:

[ ], Grants Management Specialist
Grants Management Branch, Procurement and Grants Office
Announcement Number [ ]
Centers for Disease Control and Prevention (CDC)

2920 Brandywine Road, Room 3000
Atlanta, Georgia 30341-4146

CDC does not guarantee to accept or justify its nonacceptance of recommendations that are received more than 60 days after the application deadline.

AR-8: Public Health System Reporting Requirements

This program is subject to the Public Health System Reporting Requirements. Under these requirements, all community-based non-governmental organizations submitting health services applications must prepare and submit the items identified below to the head of the appropriate State and/or local health agency(s) in the program area(s) that may be impacted by the proposed project no later than the application deadline date of the Federal application. The appropriate State and/or local health agency is determined by the applicant. The following information must be provided:

1. A copy of the face page of the application (SF 424).
2. A summary of the project that should be titled "Public Health System Impact Statement" (PHSIS), not exceed one page, and include the following:
   1. A description of the population to be served;
   2. A summary of the services to be provided; and
   3. A description of the coordination plans with the appropriate state and/or local health agencies.

If the State and/or local health official should desire a copy of the entire application, it may be obtained from the State Single Point of Contact (SPOC) or directly from the applicant.

If the program is not subject to the requirement, place the following in the section:

This program is not subject to the Public Health System Reporting Requirements.

AR-9: Paperwork Reduction Act Requirements

Projects that involve data collection from 10 or more persons and that are funded by grants and cooperative agreements will be subject to review and approval by the Office of Management and Budget (OMB).

If information is being collected from 10 or more persons and CDC has not received OMB approval, use the following:

If a cooperative agreement:

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a cooperative agreement will be subject to review and approval by the Office of Management and Budget (OMB).

If a grant:

Under the Paperwork Reduction Act, projects that involve the collection of information from 10 or more individuals and funded by a grant will be subject to review and approval by the Office of Management and Budget (OMB).

If OMB approval has already been obtained for data collection resulting from this program:

Data collection initiated under this grant/cooperative agreement) has been approved by the Office of Management and Budget (OMB) under OMB number (0920-xxxx for CDC and 0923-xxxx for ATSDR), (insert title of clearance request), (insert expiration date).

If OMB clearance is pending:

OMB clearance for the data collection initiated under this grant/cooperative agreement is pending approval by OMB.

AR-10: Smoke-Free Workplace Requirements

CDC strongly encourages all recipients to provide a smoke-free workplace and to promote abstinence from all tobacco products. Public Law 103-227, the Pro-Children Act of 1994, prohibits smoking in certain facilities that receive Federal funds in which education, library, day care, health care, or early childhood development services are provided to children.

AR-11: Healthy People 2000

CDC is committed to achieving the health promotion and disease prevention objectives of "Healthy People 2000," a national activity to reduce morbidity and mortality and improve the quality of life. For a copy of "Healthy People 2000" (Full Report: Stock No. 017-001-00474-0) or "Healthy People 2000" (Summary Report: Stock No. 017-001-00473-1), write or call:

Superintendent of Documents
Government Printing Office
Washington, DC 20402-9325
Telephone (202) 512-1800

AR-12: Lobbying Restrictions

Applicants should be aware of restrictions on the use of HHS funds for lobbying of Federal or State legislative bodies. Under the provisions of 31 U.S.C. Section 1352, recipients (and their subtier contractors) are prohibited from using appropriated Federal funds (other than profits from a Federal contract) for lobbying congress or any Federal agency in connection with the award of a particular contract, grant, cooperative agreement, or loan. This includes grants/cooperative agreements that, in whole or in part, involve conferences for which Federal funds cannot be used directly or indirectly to encourage participants to lobby or to instruct participants on how to lobby.

In addition no part of CDC appropriated funds, shall be used, other than for normal and recognized executive-legislative relationships, for publicity or propaganda purposes, for the preparation, distribution, or use of any kit, pamphlet, booklet, publication, radio, television, or video presentation designed to support or defeat legislation pending before the Congress or any State or local legislature, except in presentation to the Congress or any State or local legislature itself. No part of the appropriated funds shall be used to pay the salary or expenses of any grant or contract recipient, or agent acting for such recipient, related to any activity designed to influence legislation or appropriations pending before the Congress or any State or local legislature.

Any activity designed to influence action in regard to a particular piece of pending legislation would be considered "lobbying." That is lobbying for or against pending legislation, as well as indirect or "grass roots" lobbying efforts by award recipients that are directed at inducing members of the public to contact their elected representatives at the Federal or State levels to urge support of, or opposition to, pending legislative proposals is prohibited. As a matter of policy, CDC extends the prohibitions to lobbying with respect to local legislation and local legislative bodies.

The provisions are not intended to prohibit all interaction with the legislative branch, or to prohibit educational efforts pertaining to public health. Clearly there are circumstances when it is advisable and permissible to provide information to the legislative branch in order to foster implementation of prevention strategies to promote public health. However, it would not be permissible to influence, directly or indirectly, a specific piece of pending legislation

It remains permissible to use CDC funds to engage in activity to enhance prevention; collect and analyze data; publish and disseminate results of research and surveillance data; implement prevention strategies; conduct community outreach services; provide leadership and training, and foster safe and healthful environments.

Recipients of CDC grants and cooperative agreements need to be careful to prevent CDC funds from being used to influence or promote pending legislation. With respect to conferences, public events, publications, and "grassroots" activities that relate to specific legislation, recipients of CDC funds should give close attention to isolating and separating the appropriate use of CDC funds from non-CDC funds. CDC also cautions recipients of CDC funds to be careful not to give the appearance that CDC funds are being used to carry out activities in a manner that is prohibited under Federal law.

AR-13: Prohibition on Use of CDC Funds for Certain Gun Control Activities

The Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 1998, specifies that: "None of the funds made available for injury prevention and control at the Centers for Disease Control and Prevention may be used to advocate or promote gun control."

Anti-Lobbying Act requirements prohibit lobbying Congress with appropriated Federal monies. Specifically, this Act prohibits the use of Federal funds for direct or indirect communications intended or designed to influence a member of Congress with regard to specific Federal legislation. This prohibition includes the funding and assistance of public grassroots campaigns intended or designed to influence members of Congress with regard to specific legislation or appropriation by Congress.

In addition to the restrictions in the Anti-Lobbying Act, CDC interprets the language in the CDC's 1998 Appropriations Act to mean that CDC's funds may not be spent on political action or other activities designed to affect the passage of specific Federal, State, or local legislation intended to restrict or control the purchase or use of firearms.

AR-14: Accounting System Requirements

The services of a certified public accountant licensed by the State Board of Accountancy or the equivalent must be retained throughout the project as a part of the recipient's staff or as a consultant to the recipient's accounting personnel. These services may include the design, implementation, and maintenance of an accounting system that will record receipts and expenditures of Federal funds in accordance with accounting principles, Federal regulations, and terms of the cooperative agreement or grant.

Capability Assessment

It may be necessary to conduct an on-site evaluation of some applicant organization's financial management capabilities prior to or immediately following the award of the grant or cooperative agreement. Independent audit statements from a Certified Public Accountant (CPA) for the preceding two fiscal years may also be required.

AR-15: Proof of Non-profit Status

Proof of nonprofit status must be submitted by private nonprofit organizations with the application. Any of the following is acceptable evidence of nonprofit status: (a) a reference to the applicant organization's listing in the Internal Revenue Service's (IRS) most recent list of tax-exempt organizations described in section 501(c)(3) of the IRS Code; (b) a copy of a currently valid IRS tax exemption certificate; (c) a statement from a State taxing body, State Attorney General, or other appropriate State Official certifying that the applicant organization has a non-profit status and that none of the net earnings accrue to any private shareholders or individuals; (d) a certified copy of the organization's certificate of incorporation or similar document that clearly establishes nonprofit status; (e) any of the above proof for a State or national parent organization and a statement signed by the parent organization that the applicant organization is a local nonprofit affiliate.

AR-16: Security Clearance Requirement

All individuals who will be performing work under a grant or cooperative agreement in a CDC-owned or leased facility (on-site facility) must receive a favorable security clearance, and meet all security requirements. This means that all awardee employees, fellows, visiting researchers, interns, etc., no matter the duration of their stay at CDC must undergo a security clearance process.

AR-17: Peer and Technical Reviews of Final Reports of Health Studies - ATSDR

Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA), as amended by Superfund Amendments and Reauthorization Act of 1986 (SARA), Section 104 (I)(13), and [42 U.S.C. 9604 (I)] requires all studies and results of research (other than public health assessments) that ATSDR carries out or funds in whole or in part will be peer reviewed by ATSDR. The ATSDR peer review process for final reports requires that:

1. Studies must be reported or adopted only after appropriate peer review.

2. Studies shall be peer reviewed within a period of 60 days to the maximum extent practical.

3. Studies shall be reviewed by no fewer than three or more than seven reviewers who:
    a. are selected by the Assistant Administrator, ATSDR;
    b. are disinterested scientific experts;
    c. have a reputation for scientific objectivity; and
    d. who lack institutional ties with any person involved in the conduct of the study or research under review.

ATSDR encourages rapid reporting and interpretation of laboratory results and reference ranges back to individual participants. However, if summary tables or distribution of laboratory results are prepared using the study data, this is considered a preliminary finding and will require ATSDR technical and peer review prior to release.

When, in the opinion of the investigator(s), a public health concern exists requiring the release of summary study statistics prior to the completion of the study, the investigator must obtain concurrence from ATSDR prior to releasing the summary statistics. A request for ATSDR concurrence for the release of information must be documented in a letter to ATSDR and should outline the public health concern, the investigator's interpretation of the concern and recommended response, and the draft document proposed for release by the investigator. ATSDR will provide a technical review and peer review within ten working days to the maximum extent possible. At sites where ATSDR must coordinate with another Federal agency, this require additional time. Summary statistics may be released only after peer review. The release of summary statistics does not preclude the requirement for a final report.

By statute, the reporting of preliminary studies and preliminary research results to the public is not acceptable without prior review by ATSDR. This includes manuscripts prepared for publication, presentations at scientific meetings and reporting of preliminary findings to the community or the media.

Final Report

1. The final report for every study should include a detailed description of the problem, hypothesis, methods, results, conclusions, and recommendations that constitute a complete performance record of the study. A copy of the suggested format for the final report will be supplied by ATSDR to the investigator.

2. ATSDR is responsible for the technical and peer review of the draft final reports of any study that it funds prior to the submission of the final report. This will allow the recipient to incorporate technical and peer review comments into the final report. Responses to all ATSDR required technical and peer review comments should be summarized in a letter to ATSDR. This letter should also include the investigator's response to each comment and a rationale for those responses. Based upon the comments of the technical and peer reviewers, modifications in the study report may result. The modified study report should accompany the letter to ATSDR.

3. Following the steps outlined above, a final report of all studies and results of research carried out or supported by ATSDR must be submitted to the Procurement and Grants Office with a copy furnished to ATSDR.

All requirements, including peer review, technical review, and cost recovery, are applicable to award recipients and any subcontractors employed by the award recipient. Failure to comply with these requirements could adversely affect future funding.

AR-18: Cost Recovery - ATSDR

CERCLA, as amended by SARA, provides for the recovery of costs incurred for response actions at each Superfund site from potentially responsible parties. The recipient would agree to maintain an accounting system that will keep an accurate, complete, and current accounting of all financial transactions on a site-specific basis, i.e., individual time, travel, and associated cost including indirect cost, as appropriate for the site. The recipient would also maintain documentation that describes the site-specific response actions taken with respect to the site, e.g., contracts, work assignments, progress reports, and other documents that describe the work performed at a site. The recipient will retain the documents and records to support these financial transactions and documentation of work performed, for possible use in a cost recovery case, for a minimum of ten years after submission of a final financial status report, unless there is litigation, claim, negotiation, audit or other action involving the specific site, then the records will be maintained until resolution of all issues on the specific site.

AR-19: Third Party Agreements - ATSDR

Applicant must justify the need to use a contractor. If contractors are proposed, the following must be provided: (1) name of contractor, (2) method of selection, (3) period of performance, (4) detailed budget, (5) justification for use of contractor, and (6) assurance of non-conflict of interest.

Project activities which are approved for contracting pursuant to the prior approval provisions shall be formalized in a written agreement that clearly establishes the relationship between the recipient and the third party.

The written agreement shall, at a minimum:

1. State or incorporate by reference all applicable requirements imposed on the contractors under the terms of the grant and/or cooperative agreement, including requirements concerning technical review (ATSDR selected reviewers), ownership of data, and the arrangement for copyright when publications, data, or other copyrightable works are developed under or in the course of work under a PHS grant-supported project or activity.

2. State that any copyrighted or copyrightable works shall be subject to a royalty-free, nonexclusive, and irrevocable license to the government to reproduce, publish, or otherwise use them, and to authorize others to do so for Federal government purposes.

3. State that whenever any work subject to this copyright policy may be developed in the course of a grant by a contractor under a grant, the written agreement (contract) must require the contractor to comply with these requirements and can in no way diminish the government's right in that work.

4. State the activities to be performed, the time schedule for those activities, the policies and procedures to be followed in carrying out the agreement, and the maximum amount of money for which the grantee may become liable to the third party under the agreement.

5. State non-conflict of interest concerning activities conducted for ATSDR and site-remediation activities for other parties.

   The written agreement required shall not relieve the recipient of any part of its responsibility or accountability to PHS under the cooperative agreement. The agreement shall, therefore, retain sufficient rights and control to the recipient to enable it to fulfill this responsibility and accountability.

AR-20: Conference Support

The purpose of conference support funding is to provide PARTIAL support for specific nonfederal conferences in the areas of health promotion and disease prevention information/education programs. Because conference support by CDC creates the appearance of CDC co-sponsorship, there will be active participation by CDC in the development and approval of those portions of the agenda supported by CDC funds. CDC funds will not be expended for nonapproved portions of meetings. In addition, CDC will reserve the right to approve or reject the content of the full agenda, press events, promotional materials (including press releases), speaker selection, and site selection. Contingency awards will be made allowing usage of only 10% of the total amount to be awarded until a final full agenda is approved by CDC. This 10% portion will provide funds to support costs associated with preparation of the agenda. The remainder of funds will be released only upon approval of the final full agenda. CDC reserves the right to terminate cosponsorship if it does not concur with the final agenda.

Any conference sponsored by CDC or ATSDR shall be held in facilities that are fully accessible to the public as required by the Americans with Disabilities Act Accessibility Guidelines (ADAAG). Accessibility as per ADAAG also addresses accommodations for persons with sensory impairments.

The conference organizer(s) may use CDC's name only in factual publicity for the conference, and they should understand that CDC involvement in the conference does not necessarily indicate support for the organizer's general policies, activities, products, or service.

AR-21: Small, Minority, And Women-owned Business

It is a national policy to place a fair share of purchases with small, minority and women-owned business firms. The Department of Health and Human Services is strongly committed to the objective of this policy and encourages all recipients of its grants and cooperative agreements to take affirmative steps to ensure such fairness. In particular, recipients should:

1. Place small, minority, women-owned business firms on bidders mailing lists.

2. Solicit these firms whenever they are potential sources of supplies, equipment, construction, or services.

3. Where feasible, divide total requirements into smaller needs, and set delivery schedules that will encourage participation by these firms.

4. Use the assistance of the Minority Business Development Agency of the Department of Commerce, the Office of Small and Disadvantaged Business Utilization, DHHS, and similar state and local offices.

APPENDIX IV
Federal Act

APPENDIX CONTENT

GOVERNMENT IN THE SUNSHINE ACT

s 1. Short title

This Act may be cited as the "Government in the Sunshine Act."

s 2. Declaration of policy

It is hereby declared to be the policy of the United States that the public is entitled to the fullest practicable information regarding the decision making processes of the Federal Government. It is the purpose of this Act to provide the public with such information while protecting the rights of individuals and the ability of the Government to carry out its responsibilities.

s 3. Open meetings

(a) Title 5, United States Code, is amended by adding after section 552a the following new section:

"ss 552b. Open meetings

"(a) For purposes of this section—

"(1) the term "agency" means any agency, as defined in section 552(e) of this title, headed by a collegial body composed of two or more individual members, a majority of whom are appointed to such position by the President with the advice and consent of the Senate, and any subdivision thereof authorized to act on behalf of the agency;

"(2) the term "meeting" means the deliberations of at least the number of individual agency members required to take action on behalf of the agency where such deliberations determine or result in the joint conduct or disposition of official agency business, but does not include deliberations required or permitted by subsection (d) or (e); and

"(3) the term "member" means an individual who belongs to a collegial body heading an agency.

"(b) Members shall not jointly conduct or dispose of agency business other than in accordance with this section. Except as provided in subsection (c), every portion of every meeting of an agency shall be open to public observation.

"(c) Except in a case where the agency finds that the public interest requires otherwise, the second sentence of subsection (b) shall not apply to any portion of any agency meeting, and the requirements of subsections (d) and (e) shall not apply to any information pertaining to such meeting otherwise required by this section to be disclosed to the public, where the agency properly determines that such portion or portions of its meeting or the disclosure of such information is likely to—

"(1) disclose matters that are (A) specifically authorized under criteria established by an Executive order to be kept secret in the interests of national defense or foreign policy and (B) in fact properly classified pursuant to such Executive order;

"(2) relate solely to the internal personnel rules and practices of an agency;

"(3) disclose matters specifically exempted from disclosure by statute (other than section 552 of this title), provided that such statute (A) requires that the matters withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;

"(4) disclose trade secrets and commercial or financial information obtained from a person and privileged or confidential;

"(5) involve accusing any person of a crime, or formally censuring any person;

"(6) disclose information of a personal nature where disclosure would constitute a clearly unwarranted invasion of personal privacy;

"(7) disclose investigatory records compiled for law enforcement purposes, or information which if written would be contained in such records, but only to the extent that the production of such records or information would (A) interfere with enforcement proceedings, (B) deprive a person of a right to a fair trial or an impartial adjudication, © constitute an unwarranted invasion of personal privacy, (D) disclose the identity of a confidential source and, in the case of a record compiled by a criminal law enforcement authority in the course of a criminal investigation, or by an agency conducting a lawful national security intelligence investigation, confidential information furnished only by the confidential source, (E) disclose investigative techniques and procedures, or (F) endanger the life or physical safety of law enforcement personnel;

"(8) disclose information contained in or related to examination, operating, or condition reports prepared by, on behalf of, or for the use of an agency responsible for the regulation or supervision of financial institutions;

"(9) disclose information the premature disclosure of which would–

"(A) in the case of an agency which regulates currencies, securities, commodities, or financial institutions, be likely to (I) lead to significant financial speculation in currencies, securities, or commodities, or (ii) significantly endanger the stability of any financial institution; or

"(B) in the case of any agency, be likely to significantly frustrate implementation of a proposed agency action,

except that subparagraph (B) shall not apply in any instance where the agency has already disclosed to the public the content or nature of its proposed action, or where the agency is required by law to make such disclosure on its own initiative prior to taking final agency action on such proposal; or

"(10) specifically concern the agency's issuance of a subpoena, or the agency's participation in a civil action or proceeding, an action in a foreign court or international tribunal, or an arbitration, or the initiation, conduct, or disposition by the agency of a particular case of formal agency adjudication pursuant to the procedures in section 554 of this title or otherwise involving a determination on the record after opportunity for a hearing.

"(d)(1) Action under subsection © shall be taken only when a majority of the entire membership of the agency (as defined in subsection (a)(1)) votes to take such action. A separate vote of the agency members shall be taken with respect to each agency meeting a portion or portions of which are proposed to be closed to the public pursuant to subsection (c), or with respect to any information which is proposed to be withheld under subsection (c). A single vote may be taken with respect to a series of meetings, a portion or portions of which are proposed to be closed to the public, or with respect to any information concerning such series of meetings, so long as each meeting in such series involves the same particular matters and is scheduled to be held no more than thirty days after the initial meeting in such series. The vote of each agency member participating in such vote shall be recorded and no proxies shall be allowed.

"(2) Whenever any person whose interests may be directly affected by a portion of a meeting requests that the agency close such portion to the public for any of the reasons referred to in paragraph (5), (6), or (7) of subsection (c), the agency, upon request of any one of its members, shall vote by recorded vote whether to close such meeting.

"(3) Within one day of any vote taken pursuant to paragraph (1) or (2), the agency shall make publicly available a written copy of such vote reflecting the vote of each member on the question. If a portion of a meeting is to be closed to the public, the agency shall, within one day of the vote taken pursuant to paragraph (1) or (2) of this subsection, make publicly available a full written explanation of its action closing the portion together with a list of all persons expected to attend the meeting and their affiliation.

"(4) Any agency, a majority of whose meetings may properly be closed to the public pursuant to paragraph (4), (8), (9)(A), or (10) of subsection (c), or any combination thereof, may provide by regulation for the closing of such meetings or portions thereof in the event that a majority of the members of the agency votes by recorded vote at the beginning of such meeting, or portion thereof, to close the exempt portion or portions of the meeting, and a copy of such vote, reflecting the vote of each member on the question, is made available to the public. The provisions of paragraphs (1), (2), and (3) of this subsection and subsection (e) shall not apply to any portion of a meeting to which such regulations apply: *Provided*, That the agency shall, except to the extent that such information is exempt from disclosure under the provisions of subsection (c), provide the public with public announcement of the time, place, and subject matter of the meeting and of each portion thereof at the earliest practicable time.

"(e)(1) In the case of each meeting, the agency shall make public announcement, at least one week before the meeting, of the time, place, and subject matter of the meeting, whether it is to be open or closed to the public, and the name and phone number of the official designated by the agency to respond to requests for information about the meeting. Such announcement shall be made unless a majority of the members of the agency determines by a recorded vote that agency business requires that such meeting be called at an earlier date, in which case the agency shall make public announcement of the time, place, and subject matter of such meeting, and whether open or closed to the public, at the earliest practicable time.

"(2) The time or place of a meeting may be changed following the public announcement required by paragraph (1) only if the agency publicly announces such change at the earliest practicable time. The subject matter of a meeting, or the determination of the agency to open or close a meeting, or portion of a meeting, to the public, may be changed following the public announcement required by this subsection only if (A) a majority of the entire membership of the agency determines by a recorded vote that agency business so requires and that no earlier announcement of the change was possible, and (B) the agency publicly announces such change and the vote of each member upon such change at the earliest practicable time.

"(3) Immediately following each public announcement required by this subsection, notice of the time, place, and subject matter of a meeting, whether the meeting is open or closed, any change in one of the preceding, and the name and phone number of the official designated by the agency to respond to requests for information about the meeting, shall also be submitted for publication in the Federal Register.

"(f) (1) For every meeting closed pursuant to paragraphs (1) through (10) of subsection (c), the General Counsel or chief legal officer of the agency shall publicly certify that, in his or her opinion, the meeting may be closed to the public and shall state each relevant exemptive provision. A copy of such certification, together with a statement from the presiding officer of the meeting setting forth the time and place of the meeting, and the persons present, shall be retained by the agency. The agency shall maintain a complete transcript or electronic recording adequate to record fully the proceedings of each meeting, or portion of a meeting, closed to the public pursuant to paragraph (8), (9)(A), or (10) of subsection (c), the agency shall maintain either such a transcript or recording, or a set of minutes. Such minutes shall fully and clearly describe all matters discussed and shall provide a full and accurate summary of any actions taken, and the reasons therefor, including a description of each of the views expressed on any item and the record of any roll call vote (reflecting the vote of each member on the question). All documents considered in connection with any action shall be identified in such minutes.

"(2) The agency shall make promptly available to the public, in a place easily accessible to the public, the transcript, electronic recording, or minutes (as required by paragraph (1)) of the discussion of any item on the agenda, or of any item of the testimony of any witness received at the meeting, except for such item or items of such discussion or testimony as the agency determines to contain information which may be withheld under subsection (c). Copies of such transcript, or minutes, or a transcription of such recording disclosing the identity of each speaker, shall be furnished to any person at the actual cost of duplication or transcription. The agency shall maintain a complete verbatim copy of the transcript, a complete copy of the minutes, or a

complete electronic recording of each meeting, or portion of a meeting, closed to the public, for a period of at least two years after such meeting, or until one year after the conclusion of any agency proceeding with respect to which the meeting or portion was held, whichever occurs later.

"(g) Each agency subject to the requirements of this section shall, within 180 days after the date of enactment of this section, following consultation with the Office of the Chairman of the Administrative Conference of the United States and published notice in the Federal Register of at least thirty days and opportunity for written comment by any person, promulgate regulations to implement the requirements of subsections (b) through (f) of this section. Any person may bring a proceeding in the United States District Court for the District of Columbia to require an agency to promulgate such regulations if such agency has not promulgated such regulations within the time period specified herein. Subject to any limitations of time provided by law, any person may bring a proceeding in the United States Court of Appeals for the District of Columbia to set aside agency regulations issued pursuant to this subsection that are not in accord with the requirements of subsections (b) through (f) of this section and to require the promulgation of regulations that are in accord with such subsections.

"(h)(1) The district course of the United States shall have jurisdiction to enforce the requirements of subsections (b) through (f) of this section by declaratory judgment, injunctive relief, or other relief as may be appropriate. Such actions may be brought by any person against an agency prior to, or within sixty days after, the meeting out of which the violation of this section arises, except that if public announcement of such meeting is not initially provided by the agency in accordance with the requirements of this section, such action may be instituted pursuant to this section at any time prior to sixty days after any public announcement of such meeting. Such actions may be brought in the district court of the United States for the district in which the agency meeting is held or in which the agency in question has its headquarters, or in the District Court for the District of Columbia. In such actions a defendant shall serve his answer within thirty days after the service of the complaint. The burden is on the defendant to sustain his action. In deciding such cases the court may examine in camera any portion of the transcript, electronic recording, or minutes of a meeting closed to the public, and may take such additional evidence as it deems necessary. The court, having due regard for orderly administration and the public interest, as well as the interests of the parties, may grant such equitable relief as it deems appropriate, including granting an injunction against future violations of this section or ordering the agency to make available to the public such portion of the transcript, recording, or minutes of a meeting as is not authorized to be withheld under subsection © of this section.

"(2) Any Federal court otherwise authorized by law to review agency action may, at the application of any person properly participating in the proceeding pursuant to other applicable law, inquire into violations by the agency of the requirements of this section and afford such relief as it deems appropriate. Nothing in this section authorizes any Federal court having jurisdiction solely on the basis of paragraph (1) to set aside, enjoin, or invalidate any agency action (other than an action to close a meeting or to withhold information under this section) taken or discussed at any agency meeting out of which the violation of this section arose.

"(I) The court may assess against any party reasonable attorney fees and other litigation costs reasonably incurred by any other party who substantially prevails in any action brought in accordance with the provisions of subsection (g) or (h) of this section, except that costs may be assessed against the plaintiff only where the court finds that the suit was initiated by the plaintiff primarily for frivolous or dilatory purposes. In the case of assessment of costs against an agency, the costs may be assessed by the court against the United States.

"(j) Each agency subject to the requirements of this section shall annually report to Congress regarding its compliance with such requirements, including a tabulation of the total number of agency meetings open to the public, the total number of meetings closed to the public, the reasons for closing such meetings, and a description of any litigation brought against the agency under this section, including any costs assessed against the agency in such litigation (whether or not paid by the agency).

"(k) Nothing herein expands or limits the present rights of any person under section 552 of this title, except that the exemptions set forth in subsection © of this section shall govern in the case of any request made pursuant to section 552 to copy or inspect the transcripts, recordings, or minutes described in subsection (f) of this section. The requirements of chapter 33 of title 44, United States Code, shall not apply to the transcripts, recordings, and minutes described in subsection (f) of this section.

"(l) This section does not constitute authority to withhold any information from Congress, and does not authorize the closing of any agency meeting or portion thereof required by any other provision of law to be open.

"(m) Nothing in this section authorizes any agency to withhold from any individual any record, including transcripts, recordings, or minutes required by this section, which is otherwise accessible to such individual under section 552a of this title.".

(b) The chapter analysis of chapter 5 of title 5, United States Code, is amended by inserting:

"552b. Open meetings."

Immediately below:

"552a. Records about individuals.".

s 4. Ex parte communications

(a) Section 557 of title 5, United States Code, is amended by adding at the end thereof the following new subsection:

"(d)(1) In any agency proceeding which is subject to subsection (a) of this section, except to the extent required for the disposition of ex parte matters as authorized by law—

"(A) no interested person outside the agency shall make or knowingly cause to be made to any member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, an ex parte communication relevant to the merits of the proceeding;

"(B) no member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of the proceeding, shall make or knowingly use to be made to any interested person outside the agency an ex parte communication relevant to the merits of the proceeding:"

"(C) a member of the body comprising the agency, administrative law judge, or other employee who is or may reasonably be expected to be involved in the decisional process of such proceeding who receives, or who makes or knowingly causes to be made, a communication prohibited by this subsection shall place on the public record of the proceeding:

"(I) all such written communications;

"(ii) memoranda stating the substance of all such oral communications; and

"(iii) all written responses, and memoranda stating the substance of all oral responses, to the materials described in clauses (I) and (I) of this subparagraph;

"(D) upon receipt of a communication knowingly made or knowingly caused to be made by a party in violation of this subsection, the agency, administrative law judge, or other employee presiding at the hearing may, to the extent consistent with the interests of justice and the policy of the underlying statutes, require the party to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected on account of such violation; and

"(E) the prohibitions of this subsection shall apply beginning at such time as the agency may designate, but in no case shall they begin to apply later than the time at which a proceeding is noticed for hearing unless the person responsible for the communication has knowledge that it will be noticed, in which case the prohibitions shall apply beginning at the time of his acquisition of such knowledge.

"(2) This subsection does not constitute authority to withhold information from Congress.".

(b) Section 551 of title 5, United States Code, is amended—

(1) by striking out "and" at the end of paragraph (12);(2) by striking out the "act." at the end of paragraph (13) and inserting in lieu thereof "act; and"; and

(3) by adding at the end thereof the following new paragraph:

"(14) "ex parte communication" means an oral or written communication not on the public record with respect to which reasonable prior notice to all parties is not given, but it shall not include requests for status reports on any matter or proceeding covered by this subchapter."

© Section 556(d) of title 5, United States Code, is amended by inserting between the third and fourth sentences thereof the following new sentence: "The agency may, to the extent consistent with the interests of justice and the policy of the underlying statutes administered by the agency, consider a violation of section 557(d) of this title sufficient grounds for a decision adverse to a party who has knowingly committed such violation or knowingly caused such violation to occur."

s 5. Conforming amendments

(a) Section 410(b)(1) of title 39, United States Code, is amended by inserting after "Section 552 (public information)," the words "section 552a (records about individuals), section 552b (open meetings)."

(b) Section 552(b)(3) of title 5, United States Code, is amended to read as follows:

"(3) specifically exempted from disclosure by statute (other than section 552b of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld;"

© Subsection (d) of section 10 of the Federal Advisory Committee Act is amended by striking out the first sentence and inserting in lieu thereof the following: "Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection © of section 552b of title 5, United States Code."

s 6. Effective date

(a) Except as provided in subsection (b) of this section, the provisions of this Act shall take effect 180 days after the date of its enactment.

(b) Subsection (g) of section 552b of title 5, United States Code, as added by section 3(a) of this Act, shall take effect upon enactment.

Approved September 13, 1976.

"FEDERAL ADVISORY COMMITTEE ACT"

s 1. Short title

This Act may be cited as the "Federal Advisory Committee Act".

s 2. Findings and purpose

(a) The Congress finds that there are numerous committees, boards, commissions, councils, and similar groups which have been established to advise officers and agencies in the executive branch of the Federal Government and that they are frequently a useful and beneficial means of furnishing expert advice, ideas, and diverse opinions to the Federal Government.

(b) The Congress further finds and declares that—

(1) the need for many existing advisory committees has not been adequately reviewed; (2) new advisory committees should be established only when they are determined to be essential and their number should be kept to the minimum necessary; (3) advisory committees should be terminated when they are no longer carrying out the purposes for which they were established; (4) standards and uniform procedures should govern the establishment, operation, administration, and duration of advisory committees; (5) the Congress and the public should be kept informed with respect to the number, purpose, membership, activities, and cost of advisory committees; and (6) the function of advisory committees should be advisory only, and that all matters under their consideration should be determined, in accordance with law, by the official, agency, or officer involved.

s 3. Definitions

For the purpose of this Act—

(1) The term "Administrator" means the Administrator of General Services. (2) The term "advisory committee" means any committee, board, commission, council, conference, panel, task force, or other similar group, or any subcommittee or other subgroup thereof (hereafter in this paragraph referred to as "committee"), which is–

(A) established by statute or reorganization plan, or

(B) established or utilized by the President, or

© established or utilized by one or more agencies, in the interest of obtaining advice or recommendations for the President or one or more agencies or officers of the Federal Government, except that such term excludes (I) the Advisory Commission on Intergovernmental Relations, (ii) the Commission on Government Procurement, and (iii) any committee which is composed wholly of full-time officers or employees of the Federal Government. (3) The term "agency" has the same meaning as in section 551(1) of Title 5. (4) The term "Presidential advisory committee" means an advisory committee which advises the President.

s 4. Applicability; restrictions

(a) The provisions of this Act or of any rule, order, or regulation promulgated under this Act shall apply to each advisory committee except to the extent that any Act of Congress establishing any such advisory committee specifically provides otherwise.

(b) Nothing in this Act shall be construed to apply to any advisory committee established or utilized by–

(1) the Central Intelligence Agency; or

(2) the Federal Reserve System. © Nothing in this Act shall be construed to apply to any local civic group whose primary function is that of rendering a public service with respect to a Federal program, or any State or local committee, council, board, commission, or similar group established to advise or make recommendations to State or local officials or agencies.

s 5. Responsibilities of Congressional committees; review; guidelines

(a) In the exercise of its legislative review function, each standing committee of the Senate and the House of Representatives shall make a continuing review of the activities of each advisory committee under its jurisdiction to determine whether such advisory committee should be abolished or merged with any other advisory committee, whether the responsibilities of such advisory committee should be revised, and whether such advisory committee performs a necessary function not already being performed. Each such standing committee shall take appropriate action to obtain the enactment of legislation necessary to carry out the purpose of this subsection. (b) In considering legislation establishing, or authorizing the establishment of any advisory committee, each standing committee of the Senate and of the House of Representatives shall determine, and report such determination to the Senate or to the House of Representatives, as the case may be, whether the functions of the proposed advisory committee are being or could be performed by one or more agencies or by an advisory committee already in existence, or by enlarging the mandate of an existing advisory committee. Any such legislation shall—

(1) contain a clearly defined purpose for the advisory committee;

(2) require the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee;

(3) contain appropriate provisions to assure that the advice and recommendations of the advisory committee will not be inappropriately influenced by the appointing authority or by any special interest, but will instead be the result of the advisory committee's independent judgment;

(4) contain provisions dealing with authorization of appropriations, the date for submission of reports (if any), the duration of the advisory committee, and the publication of reports and other materials, to the extent that the standing committee determines the provisions of section 10 of this Act to be inadequate; and

(5) contain provisions which will assure that the advisory committee will have adequate staff (either supplied by an agency or employed by it), will be provided adequate quarters, and will have funds available to meet its other necessary expenses.

© To the extent they are applicable, the guidelines set out in subsection

(b) of this section shall be followed by the President, agency heads, or other Federal officials in creating an advisory committee.

s 6. Responsibilities of the President; report to Congress; annual report to Congress; exclusion

(a) The President may delegate responsibility for evaluating and taking action, where appropriate, with respect to all public recommendations made to him by Presidential advisory committees.

(b) Within one year after a Presidential advisory committee has submitted a public report to the President, the President or his delegate shall make a report to the Congress stating either his proposals for action or his reasons for inaction, with respect to the recommendations contained in the public report.

© The President shall, not later than December 31 of each year, make an annual report to the Congress on the activities, status, and changes in the composition of advisory committees in existence during the preceding fiscal year. The report shall contain the name of every advisory committee, the date of and authority for its creation, its termination date or the date it is to make a report, its functions, a reference to the reports it has submitted, a statement of whether it is an ad hoc or continuing body, the dates of its meetings, the names and occupations of its current members, and the total estimated annual cost to the United States to fund, service, supply, and maintain such committee. Such report shall include a list of those advisory committees abolished by the President, and in the case of advisory committees established by statute, a list of those advisory committees which the President recommends be abolished together with his reasons therefor. The President shall exclude from this report any information which, in his judgment, should be withheld for reasons of national security, and he shall include in such report a statement that such information is excluded.

s 7. Responsibilities of the Administrator of General Services; Committee Management Secretariat, establishment; review; recommendations to President and Congress; agency cooperation; performance guidelines; uniform pay guidelines; travel expenses; expense recommendations

(a) The Administrator shall establish and maintain within the General Services Administration a Committee Management Secretariat, which shall be responsible for all matters relating to advisory committees.

(b) The Administrator shall, immediately after October 6, 1972, institute a comprehensive review of the activities and responsibilities of each advisory committee to determine—

(1) whether such committee is carrying out its purpose;

(2) whether, consistent with the provisions of applicable statutes, the responsibilities assigned to it should be revised;

(3) whether it should be merged with other advisory committees; or

(4) whether is should be abolished.

The Administrator may from time to time request such information as he deems necessary to carry out his functions under this subsection. Upon the completion of the Administrator's review he shall make recommendations to the President and to either the agency head or the Congress with respect to action he believes should be taken. Thereafter, the Administrator shall carry out a similar review annually. Agency heads shall cooperate with the Administrator in making the reviews required by this subsection.

© The Administrator shall prescribe administrative guidelines and management controls applicable to advisory committees, and, to the maximum extent feasible, provide advice, assistance, and guidance to advisory committees to improve their performance. In carrying out his functions under this subsection, the Administrator shall consider the recommendations of each agency head with respect to means of improving the performance of advisory committees whose duties are related to such agency.

(d)(1) The Administrator after study and consultation with the Director of the Office of Personnel Management, shall establish guidelines with respect to uniform fair rates of pay for comparable services of members, staffs, and consultants of advisory committees in a manner which gives appropriate recognition to the responsibilities and qualifications required and other relevant factors. Such regulations shall provide that–

(A) no member of any advisory committee or of the staff of any advisory committee shall receive compensation at a rate in excess of the rate specified for GS-18 of the General Schedule under section 5332 of title 5, United States Code;

(B) such members, while engaged in the performance of their duties away from their homes or regular places of business, may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons employed intermittently in the Government service; and

© such members—

(I) who are blind or deaf or who otherwise qualify as handicapped individuals (within the meaning of section 501 of the Rehabilitation Act of 1973 (29 U.S.C. 794)), and

(ii) who do not otherwise qualify for assistance under section 3102 of Title 5, by reason of being an employee of an agency (within the meaning of section 3102(a)(1) of such Title 5), may be provided services pursuant to section 3102 of such Title 5 while in performance of their advisory committee duties.

(2) Nothing in this subsection shall prevent–

(A) an individual who (without regard to his service with an advisory committee) is a full-time employee of the United States, or

(B) an individual who immediately before his service with an advisory committee was such an employee, from receiving compensation at the rate at which he otherwise would be compensated (or was compensated) as a full-time employee of the United States. (e) The Administrator shall include in budget recommendations a summary of the amounts he deems necessary for the expenses of advisory committees, including the expenses for publication of reports where appropriate.

s 8. Responsibilities of agency heads; Advisory Committee Management Officer, designation

(a) Each agency head shall establish uniform administrative guidelines and management controls for advisory committees established by that agency, which shall be consistent with directives of the Administrator under section 7 and section 10. Each agency shall maintain systematic information on the nature, functions, and operations of each advisory committee within its jurisdiction.

(b) The head of each agency which has an advisory committee shall designate an Advisory Committee Management Officer who shall—

(1) exercise control and supervision over the establishment, procedures, and accomplishments of advisory committees established by that agency;

(2) assemble and maintain the reports, records, and other papers of any such committee during its existence; and

(3) carry out, on behalf of that agency, the provisions of section 552 of title 5, United States Code, with respect to such reports, records, and other papers.

s 9. Establishment and purpose of advisory committees; publication in Federal Register; charter: filing, contents, copy

(a) No advisory committee shall be established unless such establishment is—

(1) specifically authorized by statute or by the President; or

(2) determined as a matter of formal record, by the head of the agency involved after consultation with the Administrator with timely notice published in the Federal Register, to be in the public interest in connection with the performance of duties imposed on that agency by law.

(b) Unless otherwise specifically provided by statute or Presidential directive, advisory committees shall be utilized solely for advisory functions. Determinations of action to be taken and policy to be expressed with respect to matters upon which an advisory committee reports or makes recommendations shall be made solely by the President or an officer of the Federal Government.

© No advisory committee shall meet or take any action until an advisory committee charter has been filed with (1) the Administrator, in the case of Presidential advisory committees, or (2) with the head of the agency to whom any advisory committee reports and with the standing committees of the Senate and of the House of Representatives having legislative jurisdiction of such agency. Such charter shall contain the following information:

(A) the committee's official designation;

(B) the committee's objectives and the scope of its activity;

© the period of time necessary for the committee to carry out its purposes;

(D) the agency or official to whom the committee reports;

(E) the agency responsible for providing the necessary support for the committee;

(F) a description of the duties for which the committee is responsible, and, if such duties are not solely advisory, a specification of the authority for such functions;

(G) the estimated annual operating costs in dollars and man-years for such committee;

(H) the estimated number and frequency of committee meetings;

(I) the committee's termination date, if less than two years from the date of the committee's establishment; and

(J) the date the charter is filed.

A copy of any such charter shall also be furnished to the Library of Congress.

s 10. Advisory committee procedures; meetings; notice, publication in Federal Register; regulations; minutes; certification; annual report; Federal officer or employee, attendance

(a) (1) Each advisory committee meeting shall be open to the public.

(2) Except when the President determines otherwise for reasons of national security, timely notice of each such meeting shall be published in the Federal Register, and the Administrator shall prescribe regulations to provide for other types of public notice to insure that all interested persons are notified of such meeting prior thereto.

(3) Interested persons shall be permitted to attend, appear before, or file statements with any advisory committee, subject to such reasonable rules or regulations as the Administrator may prescribe.

(b) Subject to section 552 of title 5, United States Code, the records, reports, transcripts, minutes, appendixes, working papers, drafts, studies, agenda, or other documents which were made available to or prepared for or by each advisory committee shall be available for public inspection and copying at a single location in the offices of the advisory committee or the agency to which the advisory committee reports until the advisory committee ceases to exist.

© Detailed minutes of each meeting of each advisory committee shall be kept and shall contain a record of the persons present, a complete and accurate description of matters discussed and conclusions reached, and copies of all reports received, issued, or approved by the advisory committee. The accuracy of all minutes shall be certified to by the chairman of the advisory committee.

(d) Subsections (a)(1) and (a)(3) of this section shall not apply to any portion of an advisory committee meeting where the President, or the head of the agency to which the advisory committee reports, determines that such portion of such meeting may be closed to the public in accordance with subsection © of section 552b of title 5, United States Code. Any such determination shall be in writing and shall contain the reasons for such determination. If such a determination is made, the advisory committee shall issue a report at least annually setting forth a summary of its activities and such related matters as would be informative to the public consistent with the policy of section 552(b) of title 5, United States Code.

(e) There shall be designated an officer or employee of the Federal Government to chair or attend each meeting of each advisory committee. The officer or employee so designated is authorized, whenever he determines it to be in the public interest, to adjourn any such meeting. No advisory committee shall conduct any meeting in the absence of that officer or employee.

(f) Advisory committees shall not hold any meetings except at the call of, or with the advance approval of, a designated officer or employee of the Federal

s 11. Availability of transcripts; “agency proceeding”

(a) Except where prohibited by contractual agreements entered into prior to the effective date of this Act, agencies and advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of agency proceedings or advisory committee meetings.

(b) As used in this section “agency proceeding” means any proceeding as defined in section 551(12) of title 5, United States Code.

s 12. Fiscal and administrative provisions; record keeping; audit; agency support services

(a) Each agency shall keep records as will fully disclose the disposition of any funds which may be at the disposal of its advisory committees and the nature and extent of their activities. The General Services Administration, or such other agency as the President may designate, shall maintain financial records with respect to Presidential advisory committees. The Comptroller General of the United States, or any of his authorized representatives, shall have access, for the purpose of audit and examination, to any such records.

(b) Each agency shall be responsible for providing support services for each advisory committee established by or reporting to it unless the establishing authority provides otherwise. Where any such advisory committee reports to more than one agency, only one agency shall be responsible for support services at any one time. In the case of Presidential advisory committees, such services may be provided by the General Services Administration.

s 13. Responsibilities of Library of Congress; reports and background papers; depository

Subject to section 552 of title 5, United States Code, the Administrator shall provide for the filing with the Library of Congress of at least eight copies of each report made by every advisory committee and, where appropriate, background papers prepared by consultants. The Librarian of Congress shall establish a depository for such reports and papers where they shall be available to public inspection and use.

s 14. Termination of advisory committees; renewal; continuation

(a) (1) Each advisory committee which is in existence on the effective date of this Act shall terminate not later than the expiration of the two-year period following such effective date unless—

(A) in the case of an advisory committee established by the President or an officer of the Federal Government, such advisory committee is renewed by the President or that officer by appropriate action prior to the expiration of such two-year period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(2) Each advisory committee established after such effective date shall terminate not later than the expiration of the two-year period beginning on the date of its establishment unless–

(A) in the case of an advisory committee established by the President or an officer of the Federal Government such advisory committee is renewed by the President or such officer by appropriate action prior to the end of such period; or

(B) in the case of an advisory committee established by an Act of Congress, its duration is otherwise provided for by law.

(b) (1) Upon the renewal of any advisory committee, such advisory committee shall file a charter in accordance with section 9(c).

(2) Any advisory committee established by an Act of Congress shall file a charter in accordance with such section upon the expiration of each successive two-year period following the date of enactment of the Act establishing such advisory committee.

(3) No advisory committee required under this subsection to file a charter shall take any action (other than preparation and filing of such charter) prior to the date on which such charter is filed.

© Any advisory committee which is renewed by the President or any officer of the Federal Government may be continued only for successive two-year periods by appropriate action taken by the President or such officer prior to the date on which such advisory committee would otherwise terminate.

s 15. Effective date

Except as provided in section 7(b), this Act shall become effective upon the expiration of ninety days following October 6, 1972.

Charter

DISEASE, DISABILITY, AND INJURY PREVENTION AND CONTROL
SPECIAL EMPHASIS PANEL

Purpose

The Secretary of Health and Human Services is authorized under Section 301 of the Public Health Service Act (42 U.S.C. 241) to make grants-in-aid for research projects relating to health. In addition, the Secretary is authorized under Sections 306, 308, 317, 317a, 318, 391, 1501, 1701, and 1706 of the Public Health Service Act (42 U.S.C. 242k, 242m, 247b, 247b-1, 247c, 280b, 300k, 300u, 300u-5); Section 104(I) of the Comprehensive Environmental Response,
Compensation, and Liability Act (42 U.S.C. 9604(I)); and other authorities as appropriate to support grants, cooperative agreements, and studies relating to the prevention and control of diseases, disabilities, injuries, and impairments of public health significance.

This panel will review applications and proposals for research projects and for grants and cooperative agreements in the areas of the causes, prevention, and control of diseases, disabilities, injuries, and impairments of public health significance; exposure to hazardous substances in the environment; health promotion and education; and other
related activities that promote health and well-being.

Authority

42 U.S.C. 217a, Section 222 of the Public Health Service Act, as amended. The Panel is governed by the provisions of Public Law 92-463, as amended (5 U.S.C. App. 2), which sets forth standards for the formation and use of advisory committees.

Function

The Disease, Disability, and Injury Prevention and Control Special Emphasis Panel shall provide advice and guidance to the Secretary; the Assistant Secretary for Health; the Director, Centers for Disease Control and Prevention; and the Administrator, Agency for Toxic Substances and Disease Registry, regarding the scientific and technical merit of grant and cooperative agreement assistance applications relating to the causes, prevention, and control of diseases, disabilities, injuries, and impairments of public health significance; exposure to hazardous substances in the
environment; health promotion and education; and other related activities that promote health and well-being.

Structure

Members and Chairs shall be selected by the Secretary, or other official to whom the authority has been delegated, on an "as needed" basis in response to specific applications to be reviewed. The Panel will consist of approximately 460 members, of whom approximately 210 may be voting ex officio members. Members will be selected from authorities in the various fields of prevention and control of diseases, disabilities, and injuries. Members of other chartered
Department of Health and Human Services' advisory committees may serve on the Panel if their expertise is required.

Management and support services shall be provided by the Committee Management and Program Panels Activity, Centers for Disease Control and Prevention.

Meetings

Meetings shall be held as necessary (approximately 30 times per year) as determined by the Designated Federal Official, who shall also approve the agenda. A government official shall be present at all meetings.

Meetings shall be open to the public except as determined otherwise by the Secretary or other official to whom the authority has been delegated; notice of all meetings shall be given to the public.

Meetings shall be conducted, and records of the proceedings kept, as required by applicable laws and Departmental regulations.

Compensation

Members who are not full-time Federal employees shall be paid at the rate of $250 per day, plus per diem and travel expenses in accordance with Standard Government Travel Regulations.

Annual Cost Estimate

Estimated annual cost for operating the Panel, including compensation and travel expenses for members but excluding staff support, is $631,618. Estimate of annual person-years of staff support required is 2.1 at an estimated annual cost of $120,622.

Reports

In the event a portion of a meeting is closed to the public, a report shall be prepared annually which shall contain, at a minimum, a list of members and their business addresses; the Committee's functions, dates and places of meetings; and a summary of committee activities and recommendations made during the fiscal year. A copy of the report shall be provided to the Department's Committee Management Officer.

Termination Date

Unless renewed by appropriate action prior to its expiration, the Disease, Disability, and Injury Prevention and Control Special Emphasis Panel will terminate on September 18, 2002.

APPROVED:

(signed and dated September 14, 2000, by the Director, Centers for Disease Control and Prevention)

Privacy Act

The Privacy Act of 1974 (*Public Law 93-579*) is designed to safeguard individuals from invasions of personal privacy by federal agencies. This legislation permits individuals names in federal records to access their records for the following purposes:

- To determine what records pertaining to them are maintained by and used in a Federal agency;
- To prevent their records from being used for any purpose other than the intended one(s) without their permission; and
- To ascertain that the information concerning them is accurate, up to date and relevant and for it to be corrected, if necessary.

Definition of "*record"*: The term "*record*" refers to any item of information, filed by individual identifier, including handwritten notes about an individual which can be traced to him or her by name, symbol, etc. The records of most concern are those associated with the grant application peer review process. Staff or reviewers' rough notes are not considered part of the record unless they have been placed in the official files.

The following materials should not be retained in grant files:

- Preliminary written comments by reviewers;
- Diskettes of members' reviews;
- Assignment lists;
- Priority scoring sheets;
- Mail opinions; and
- Staff notes.

Implementation

To implement the Privacy Act provisions, the CDC Center should have staff responsible to oversee systems of records in order to maintain their accuracy, amend the records if necessary, respond to Privacy Act requests, and review information to be released. If the requested material is currently available and is in a systematic set of records, it must be released. The staff must respond to a written request within 10 working days of its receipt date.

Agency Responsibility

Federal agencies must collect, maintain, or use the records of identifiable persons in a lawful manner, ensure that the records are accurate, and provide safeguards to prevent misuse. If provisions of the Privacy Act are violated, Federal employees can be subject to fines up to $5,000.

Freedom of Information Act

The Freedom of Information Act (FOIA) of 1974 (*Public Law 90-23*), which is designed to allow public access to records held by Federal agencies, differs from the Privacy Act in that individuals are seeking records other than their own. Individuals may request information from Federal agencies under the act. The requestor must be informed about the action being taken on the request within 10 working days, as well as the fee schedule for copying services and record searches if the request is honored.

Records requested under the FOIA must be disclosed unless the records fall within one of nine areas of exemption. The three exemptions most relevant to the CDC grant programs are:

- Trade secrets, commercial and financial information;
- Inter- or intra-agency memoranda or letters that would be available by law only by litigation with the agency; and
- Records whose release would constitute an unwarranted invasion of privacy.

Requests are denied for pending or not funded grant applications, for information subject to Privacy Act restrictions, for records of discussions of applications by advisory bodies, for grantee research data that are not part of a formal progress report, or for any information pertaining to the exemptions above. Released material may have sections deleted, such as salary figures, because of the exemptions. Under these exemptions, for example, summary statements are not released to individuals, other than the Principal Investigator.

The following documents may be released under FOIA regulations:

- Funded applications for research or training support (defined as those for which a notice of a grant award has been issued);
- Notice of grant award;
- Progress reports;
- Reports of expenditures; and
- Audit and survey records submitted to grantee institutions.

Requests for information should be forwarded to the appropriate CDC Center staff responsible for responding to FOIA inquiries. Whenever material is released, the CDC staff should notify the grantee before releasing information. Written requests for information can be denied only after consultation with the appropriate CDC staff.